



**MEDI-CAL DRUG USE REVIEW (DUR) BOARD**

**State of California  
DEPARTMENT OF HEALTH CARE SERVICES**

Notice is hereby given that the **Medi-Cal DUR Board** will conduct a public meeting on **Tuesday, September 20, 2016**, at the following location:

Xerox State Healthcare, LLC  
840 Stillwater Road, Monterey Room  
West Sacramento, CA 95605

Medi-Cal Drug Use Review Board  
Meeting Agenda  
September 20, 2016  
9:30 AM-12:30 PM

Report Type*	Agenda Item	Presenter	Time
C	<b>1.</b> Welcome/Introduction	Pauline Chan, RPh, MBA	930-945
A	<b>2.</b> Call to Order/Review and Approval of Previous Minutes from May 17, 2016	Robert Mowers, PharmD	945-950
	<b>3.</b> Old Business		
A	<b>a.</b> Review of Action Items from Previous Board Meeting: i. Pregnancy Alert: Updated ii. Drug-Drug Interaction Alert: DUR Manual Updated iii. Anticholinergic Provider Letter: Sent iv. PCSK9 Inhibitor: Update RetroDUR in May 2017	Pauline Chan, RPh, MBA	950-955
	<b>4.</b> New Business		
R/A/D	<b>a.</b> Board Activities	DUR Board	955-1000
R/D	<b>b.</b> Managed Care Presentation: San Francisco Health Plan	Eileen Yamada, MD, MPH [Public Health Medical Officer, Technical Assistance Section, Immunization Branch California Department of Public Health]	1000-1020
R/A/D	<b>c.</b> Presentation: Medi-Cal Payment Error Study	Mark P. Mimnaugh, RN, CCRN, MPA [Chief, Medical Review Branch Audits and Investigations Division]	1020-1040

R/A/D	<b>d.</b> FFY2015 DUR Annual Report to CMS	Pauline Chan, RPh, MBA and Ivana Thompson, PharmD	1040- 1100
R/A	<b>e.</b> Quarterly Report: 2Q2016 (April – June 2016) <b>f.</b> Review of Physician Administered Drugs (PADs): 1Q2016 (January – March 2016) <b>g.</b> Prospective DUR i. Review of DUR Alerts for New GCNs: 2Q2016 <b>h.</b> Review of DUR Educational Outreach to Providers i. Update: Anticholinergic Letter ii. Updated Outcomes: Asthma Letter iii. Updated Outcomes: MEDD Letter iv. Proposal: Buprenorphine Letter <b>i.</b> Policy Impact Report: Antipsychotic TAR Requirement for Children and Adolescents	Amanda Fingado, MPH	1100- 1140
R/A/D	<b>j.</b> Retrospective DUR i. HIV Antiretroviral Drugs <b>k.</b> Review of DUR Publications i. DUR Educational Bulletin (August, 2016): Buprenorphine ii. Discussion/Recommendations for Future Bulletins	Shalini Lynch, PharmD	1140- 1200
	<b>l.</b> Pharmacy Update i. CMS Update 1. Antipsychotic Drug Use in Children (ADC) Affinity Group 2. Prescription Opioids Abuse Actions 3. 2018 CMS DUR Annual Report Planning Committee ii. DHCS Quality Strategy Annual Update iii. Child Core Set Measures iv. Adult Core Set Measures v. Academic Detailing Conference Working Agenda	Pauline Chan, RPh, MBA	1200- 1225
<b>C</b>	<b>5.</b> Public Comments		1225- 1230
	<b>6.</b> Consent Agenda		
<b>I</b>	<b>a.</b> Meeting feedback <b>b.</b> Next meeting: November 15, 2016 9:30 AM -12:30 PM DHCS Training Rooms B+C 1500 Capitol Avenue Sacramento, CA 95814 <b>c.</b> Proposed DUR Board Meeting Dates for 2017: Tuesday, February 21, 2017 Tuesday, May 16, 2017 Tuesday, September 19, 2017 Tuesday, November 21, 2017		
	<b>7.</b> Adjournment		1230

\* REPORT TYPE LEGEND: **A: Action; R: Report; I: Information; C: Comment; D: Discussion**

\*\* Comments from the public are always appreciated. However, comments will be limited to five minutes per individual.

Picture identification is required to gain access into the California Department of Health Services building. However, your security information will not be provided to the DUR Board.

You can obtain the DUR Board agenda from the Medi-Cal DUR Main Menu Web site ([http://files.medi-cal.ca.gov/pubsdoco/dur/dur\\_home.asp](http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp)).



**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 in 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

State of California  
MEDICAID DRUG UTILIZATION REVIEW

Centers for Medicare & Medicaid Services  
Federal Fiscal Year

**ANNUAL REPORT**  
**FEDERAL FISCAL YEAR 2015**

This report covers the period  
October 1, 2014 to September 30, 2015



Department of Health Care Services  
Prepared by



AND



Under the direction of the Medi-Cal Pharmacy Benefits Division, Pharmacy Policy  
Branch and the California Drug Use Review Board

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**California Medi-Cal  
Drug Use Review (DUR) Program  
Federal Fiscal Year (FFY) 2015 Annual Report  
October 1, 2014 to September 30, 2015**

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**CMS SURVEY****I. DEMOGRAPHIC INFORMATION****State Name Abbreviation**CA**Medicaid Agency Information**

Identify State person responsible for DUR Annual Report Preparation.

Name: Mike Wofford, PharmD.Email Address: [Mike.Wofford@dhcs.ca.gov](mailto:Mike.Wofford@dhcs.ca.gov)Area Code/Phone Number: (916) 552-9606**II. PROSPECTIVE DUR (ProDUR)**

Identify by name and indicate the type of your pharmacy POS vendor - (contractor, state-operated, other).

Contractor: Xerox State Healthcare, LLC

1. If not state-operated, is the POS vendor also the MMIS fiscal agent?

 Yes  No

2. Identify prospective DUR criteria source.

 First Data Bank  Medi-Span  OtherIf the answer above is "Other," please specify:  

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3. Are new prospective DUR criteria approved by the DUR Board?

 Yes  No

If answer above is "No," please explain:

The DUR board advises and makes recommendations regarding prospective DUR

criteria; however, final approval is made by DHCS.

4. When the pharmacist receives a ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "conflict, intervention and outcome" codes?

Yes  No

5. How often do you receive and review periodic reports providing individual pharmacy provider activity in summary and in detail?

Monthly  Quarterly  Annually  Never

- a) If the answer above is "Never," please explain why you do not receive and review the reports.

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- b) If you receive reports, do you follow-up with those providers who routinely override with interventions?

Yes  No

- c) If the answer to (b) above is "Yes," by what method do you follow-up?

Contact Pharmacy  
 Refer to Program Integrity for Review  
 Other, please explain.

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- d) If the answer to (b) above is "No," please explain why you do not follow-up with providers.

Beginning FY 2016, we plan to work with Xerox to follow up with providers at least annually or more often.

6. Early Refill:

- a) At what percent threshold do you set your system to edit?

Non-controlled drugs: 75 %

Controlled drugs: 75 %

b) When an early refill message occurs, does the state require prior authorization?

Non-controlled drugs:  Yes  No

Controlled drugs:  Yes  No

c) For non-controlled drugs, if the answer to (b) above is "Yes," who obtains authorization?

Pharmacist  Prescriber  Either

d) For controlled drugs, if the answer to (b) above is "Yes," who obtains authorization?

Pharmacist  Prescriber  Either

e) For non-controlled drugs, if the answer to (b) above is "No," can the pharmacist override at the point of service?

Yes  No

f) For controlled drugs, if the answer to (b) above is "No," can the pharmacist override at the point of service?

Yes  No

7. When the pharmacist receives an early refill DUR alert message that requires the Pharmacist's review, does your state's policy allow the pharmacist to override for situations such as:

a) Lost/stolen Rx  Yes  No

b) Vacation  Yes  No

c) Other, please explain: The pharmacist can override the early refill DUR alert message if medically necessary.

8. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

Yes  No

a) If "Yes," please explain your edit.

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b) If "No," do you plan to implement this edit?

Yes  No

9. Does the state or the state's Board of Pharmacy have any policy prohibiting the auto-refill process that occurs at the POS?

Yes  No

10. Has the state provided DUR data requested on **Table 1 – Top Drug Claims Data Reviewed by the DUR Board?**

Yes  No

11. Section 1927(g)(A) of the Social Security Act requires that the pharmacist offer patient counseling at the time of dispensing. Who in your state has responsibility for monitoring compliance with the oral counseling requirement? Check all that apply:

a)  Medicaid agency

b)  State Board of Pharmacy

c)  Other, please explain.

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12. Has the state included **Attachment 1 – Pharmacy Oral Counseling Compliance Report**, a report on state efforts to monitor pharmacy compliance with the oral counseling requirement?

Yes  No

### III. **RETROSPECTIVE DUR (RetroDUR)**

1. Identify, by name and type, the vendor that performed your Retro DUR activities during the time period covered by this report (company, academic institution, or other organization).

Academic institution: University of California, San Francisco (UCSF)

a) Is the Retro DUR vendor also the Medicaid fiscal agent?

Yes No

b) Is the RetroDUR vendor also the developer/supplier of your retrospective DUR criteria?

Yes No

If "No," please explain: Retrospective DUR criteria are developed jointly by UCSF and DHCS with input and recommendation by the DUR board. Final approval of criteria is made by DHCS.

2. Does the DUR Board approve the RetroDUR criteria?

Yes No

If "No," please explain: The DUR board advises and makes recommendations regarding prospective DUR criteria; however, final approval is made by DHCS.

3. Has the state included **Attachment 2 -Retrospective DUR Educational Outreach Summary**, a year end summary of the Top 10 problem types for which educational interventions were taken?

Yes No

#### IV. DUR BOARD ACTIVITY

1. State is including a brief summary of DUR Board activities and meeting minutes during the time period covered by this report as **Attachment 3 – Summary of DUR Board Activities**.

Yes No

2. Does your state have a Disease Management Program?

Yes No

a) If "Yes", have you performed an analysis of the program's effectiveness?

Yes No

b) If the answer to (a) above is "Yes", please provide a brief summary of your findings:

- 
- c) If the answer to (number 2) above is “Yes,” is your DUR Board involved with this program?

Yes                      No

3. Does your state have an approved CMS Medication Therapy Management Program?

Yes                      No

- a) If “Yes”, have you performed an analysis of the program’s effectiveness?

Yes                      No

- b) If the answer to (a) above is “Yes,” please provide a brief summary of your findings.

- 
- c) If the answer to (number 3) above is “Yes,” is your DUR Board involved with this program?

Yes                      No

- d) If the answer to (number 3) above is “No” are you planning to develop and implement a program?

Yes                      No

**V. PHYSICIAN ADMINISTERED DRUGS**

The Deficit Reduction Act required collection of NDC numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for:

1. ProDUR?

Yes                      No

If “No,” do you have a plan to include this information in your DUR criteria in the future?

- Yes                       No  
2. RetroDUR?

Yes                       No

If "No," do you have a plan to include this information in your DUR criteria in the future?

Yes                       No

## VI. GENERIC POLICY AND UTILIZATION DATA

1. State is including a description of policies that may affect generic utilization percentage as Attachment 4 - Generic Drug Substitution Policies.

Yes                       No

2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your state have a more restrictive requirement?

Yes                       No

If "Yes", check all that apply:

- a)  Require that a MedWatch Form be submitted  
b)  Require medical reason for override accompany prescriptions  
c)  Prior authorization is required  
d)  Other, please explain.

If a brand name drug does not appear on the Medi-Cal List of Contract Drugs, an approved *Treatment Authorization Request* may be required before dispensing.

3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in Table 2 – Generic Utilization Data.

Number of Generic Claims:                      8,912,490

Total Number of Claims:                      13,212,808

Generic Utilization Percentage:                      67.4%

- Indicate the percentage dollars paid for generic covered outpatient drugs in relation to all covered outpatient drug claims paid during this reporting period using the computation instructions in **Table 2 - Generic Utilization Data**.

Generic Dollars: \$335,642,597

Total Dollars: \$3,527,504,042

Generic Expenditure Percentage: 9.5%

**VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE**

- Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance?

Yes      No

- Who conducted your program evaluation for the cost savings estimate/cost avoidance (company, academic institution, other institution)?

University of California, San Francisco (UCSF)

- Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.

ProDUR Total Estimated Avoided Costs	\$217,545,867
RetroDUR Total Estimated Avoided Costs	\$0
Other cost avoidance	\$0
<b>Grand Total estimated Avoided Costs</b>	<b>\$217,545,867</b>

- Please provide the estimated percent impact of your state’s cost savings/cost avoidance program compared to total drug expenditures for covered outpatient drugs.

Use the following formula:

Divide the estimated Grand Total Estimated Avoided Costs from Question 3 above by the total dollar amount provided in Section VI, Question 4. Then multiply this number by 100.

Grand Estimated Net Savings Amount ÷ Total Dollar Amount × 100 = **6.2%**  
 (\$217,545,867 ÷ \$3,527,504,042 × 100 = 6.2%)

- State has provided the Medicaid Cost Savings/Cost Avoidance Evaluation as **Attachment 5 – Cost Savings/Cost Avoidance Methodology**.

Yes       No

### VIII. FRAUD, WASTE, AND ABUSE DETECTION

#### A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS

1. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

Yes       No

If "Yes," what action(s) does this process initiate? Check all that apply.

- a)  Deny claim and require prior authorization
- b)  Refer recipient to Lock In Program
- c)  Refer to Program Integrity Unit
- d)  Other (e.g. SURS, Office of Inspector General), please explain.

22CCR §50793 details available utilization restrictions when the Department has determined that a beneficiary is misusing or abusing Medi-Cal benefits. Audit & Investigations Branch (IB) is responsible for working beneficiary cases. IB has an intake process for complaints which entails an initial case review and if warranted, assignment of a case to an investigator. Subsequent actions are dependent upon the outcome of IB's investigation.

2. Do you have a "lock-in" program for beneficiaries with potential misuse or abuse of controlled substances?

Yes       No

If "Yes", what criteria does your state use to identify candidates for lock-in? Check all that apply.

- Number of controlled substances (CS)
- Different prescribers of CS
- Multiple pharmacies
- Number days' supply of CS
- Exclusivity of short acting opioids
- Multiple ER visits
- Other

Audit & Investigations Branch (IB) considers all of the above during their case-by-case review of beneficiary-related complaints.

If "Yes" do you restrict the beneficiary to:

- i. a prescriber only  Yes  No  
 ii. a pharmacy only  Yes  No  
 iii. a prescriber and pharmacy  Yes  No

What is the usual "lock-in" time period?

- 6 months  
 12 months  
 Other, please explain: Two years according to 22CCR§ 50793

3. On the average, what percentage of the FFS population is in lock-in status annually?  
<1 %
4. Please provide an estimate of the savings attributed to the lock-in program for the fiscal year under review. \$ unknown
5. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by **prescribers**?

Yes  No

If "Yes," what actions does this process initiate? Check all that apply.

- a)  Deny claims written by this prescriber  
 b)  Refer to Program Integrity Unit  
 c)  Refer to the appropriate Medical Board  
 d)  Other, please explain.

Propose new policy such as quantity restrictions, and further review by Audit & Investigations Branch (IB) Medical Review Branch (MRB).

6. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **pharmacy providers**?

Yes  No

If "Yes," what actions does this process initiate? Check all that apply.

- a)  Deny claim  
 b)  Refer to Program Integrity Unit

- c)  Refer to Board of Pharmacy  
d)  Other, please explain.

Propose new policy such as quantity restrictions and further review by Audit & Investigations Branch (IB) Medical Review Branch (MRB)

7. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

Yes       No

If "Yes," please explain your program for fraud, waste, or abuse of non-controlled substances.

Audit & Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations, including review of claims data and trends of non-controlled drugs.

**B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)**

1. Does your state have a Prescription Drug Monitoring Program (PDMP)?

Yes       No

- a) If the answer above is "Yes" does your agency have the ability to query the state's PDMP database?

Yes       No

- b) If the answer to (number 1) above is "Yes", do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before prescribing restricted substances?

Yes       No

- c) If the answer to (number 1) above is "Yes", please explain how the state applies this information to control fraud and abuse.

The California Department of Justice has a Prescription Drug Monitoring Program (PDMP) system called The Controlled Substance Utilization Review and Evaluation System (CURES), which allows pre-registered users including licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient controlled substance history information.

Access to such information helps prescribers and pharmacists better evaluate their patients' care, allowing them to make better prescribing and dispensing decisions, and cut down on prescription drug abuse in California.

The Audit & Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations. Audit & Investigations Branch (IB) examines PDMP information on prescribers, dispensers, and beneficiaries during the course of A&I's usual work

d) If the answer to (number 1) above is "Yes", do you also have access to border states' PDMP information?

Yes No

2. Are there barriers that hinder the agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb abuse?

Yes No

If "Yes" please explain the barriers (e.g. lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script)

Enrollment by California's prescribers and pharmacists has experienced some delays due to restructuring of the CURES program under the Department of Justice and state budgetary restrictions. A streamlined application and approval process for access to the Controlled Substance Utilization Review and Evaluation System (CURES) 2.0 is nearing completion and should be fully operational in FFY 2016.

3. Have you had any changes to your state's Prescription Drug Monitoring Program during this reporting period that have improved the agency's ability to access PDMP data?

Yes No

If "Yes" please explain.

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### C. PAIN MANAGEMENT CONTROLS

1. Does your state or your agency require that Pain Management providers be certified?

Yes       No

2. Does your program obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?

Yes       No

- a) If the answer above is "Yes," do you apply this DEA file to your ProDur POS edits to prevent unauthorized prescribing?

Yes       No

- b) If the answer to (a) above is "Yes," please explain how the information is applied
- 
- 

- c) If the answer to (a) above is "No" do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?

Yes       No

3. Do you apply this DEA file to your RetroDUR reviews?

Yes       No

If "Yes" please explain how it is applied.

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4. Do you have measures in place to either monitor or manage the prescribing of methadone for pain management?

Yes       No       Other

If "Yes," please check all that apply.

- Pharmacist override  
 Deny claim and require PA  
 Quantity limits  
 Intervention letters  
 Morphine equivalent daily dose program

Step therapy or Clinical criteria

If "No" or "Other," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of methadone for pain management.

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D. OPIOIDS

1. Do you currently have POS edits in place to limit the quantity of short-acting opioids?  
 Yes                       No

a) If "Yes," what is your maximum daily limit in terms of number of units (i.e. tablets, capsules)?

Short-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

b) If "Yes" what is your maximum days supply per prescription limitation??

30 day supply

90 day supply

Other, please explain: Short-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

2. Do you currently have POS edits in place to limit the quantity of long-acting opioids?

Yes                       No

a) If "Yes," what is your maximum daily limit in terms of number of units (i.e. tablets, capsules)?

2 units/day

3 units/day

b) If "Yes" what is your maximum days supply per prescription limitation??

30 day supply

90 day supply

Other, please explain: Long-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

3. Do you currently have edits in place to monitor opioids and benzodiazepines being used concurrently?

Yes       No

If "Yes" please explain.

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E. MORPHINE EQUIVALENT DAILY DOSE (MEDD)

1. Have you set recommended maximum morphine equivalent daily dose measures?

Yes       No

If "Yes," what is your maximum morphine equivalent daily dose limit in milligrams?

\_\_\_\_\_mg per day

If "No," please explain the measure or program you utilize.

All opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

2. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage?

Yes       No

If "Yes" how is the information disseminated?

- Website  
 Provider notice  
 Educational seminar  
 Other, please explain.

The Medi-Cal DUR program published an educational bulletin entitled, "Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse" to the Medi-Cal DUR website. This bulletin defined morphine equivalent daily dose (MEDD) and provided evidence to support using MEDD as an indicator of potential dose-related risk for prescription opioid overdose. The bulletin provided links to several online MEDD calculators, as well as additional resources to providers. The bulletin was

also emailed to all providers who subscribe to the Medi-Cal Subscription Service.

3. Do you have an algorithm in your POS system that alerts the pharmacy provider that the morphine equivalent daily dose prescribed has been exceeded?

Yes  No

F. BUPRENORPHINE and BUPRENORPHINE/NALOXONE COMBINATIONS

1. Does your agency set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

Yes  No

If "Yes", please specify the total mg/day?

- 12 mg  
 16 mg  
 24 mg  
 Other, please explain

2. What are your limitations on the allowable length of this treatment?

- 6 months  
 12 months  
 No limit  
 Other, please explain.

Until June 1, 2015, buprenorphine was dispensed only with an approved *Treatment Authorization Request*. For the remainder of FFY 2015, it was restricted to 120 dosage units (regardless of strength) and a 30 day supply per dispensing. Exceptions to this rule continue to require an approved *Treatment Authorization Request*.

3. Do you require that the maximum mg per day allowable be reduced after a set period of time?

Yes  No

- a) If "Yes," what is your reduced (maintenance) dosage?

- 8 mg  
 12 mg  
 16 mg  
 Other, please explain.

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b) If "Yes," what are your limitations on the allowable length of the reduced dosage treatment?

- 6 months  
 12 months  
 No limit  
 Other, please explain.

4. Do you have at least one preferred buprenorphine/naloxone combination product available on your PDL?

Yes  No

5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug?

Yes  No

If "Yes," can the POS pharmacist override the edit?

Yes  No

#### G. ANTIPSYCHOTICS/STIMULANTS

##### ANTIPSYCHOTICS

1. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children??

Yes  No

If "Yes," do you either manage or monitor:

- Only children in foster care  
 All children  
 Other, please explain
- 

If "Yes," do you have edits in place to monitor:

Child's Age       Dosage       Polypharmacy

Please briefly explain the specifics of your program(s).

An approved *Treatment Authorization Request* is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age.

In addition, DHCS Pharmacy Benefits Division, DHCS Behavioral Health Division, and California Department of Social Services (CDSS) continue to collaborate on a Quality Improvement Project entitled, "Improving the Use of Psychotropic Medication among Children and Youth in Foster Care." The purpose of this program is to reduce the rate of antipsychotic polypharmacy, improve the rate of compliance with age-specific antipsychotic dose recommended guidelines, and improve the rate of children and youth in foster care with at least one psychotropic medication who have an annual metabolic risk assessment. The goals are to reduce polypharmacy and improve compliance with dosing guidelines and annual metabolic risk assessment.

If you do not have an antipsychotic monitoring program in place, do you plan on implementing a program in the future?

Yes       No

If "No," please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.

## STIMULANTS

2. Do you have any documented restrictions or special program in place to monitor, manage, or control the use of stimulants?

Yes       No

If "Yes," is your program limited to:

Children  
 Adults  
 Both

Please briefly explain your program.

The use of stimulants for Medi-Cal beneficiaries is restricted to use in Attention Deficit Disorder in individuals from 4 years through 16 years of age only. Any use

outside of these restrictions requires an approved *Treatment Authorization Request*.

## **IX. INNOVATIVE PRACTICES**

Have you developed any innovative practices during the past year which you have included in **Attachment 6 - Innovative Practices** (e.g. Hepatitis C, Cystic Fibrosis, MEDD, Value Based Purchasing)?

Yes No

## **X. E-PRESCRIBING**

1. Does your MMIS or pharmacy vendor have a portal to electronically provide patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing upon inquiry?

Yes No

a) If "Yes," do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

Yes No

b) If "Yes," please explain the evaluation methodology in **Attachment 7 – E-Prescribing Activity Summary**.

c) If the answer to (number 1) above is "No," are you planning to develop this capability?

Yes No

2. Does your system use the NCPDP Origin Code that indicates the prescription source?

Yes No

## **XI. MANAGED CARE ORGANIZATIONS (MCOs)**

1. Does your state have MCOs?

Yes No

If "No," please skip the rest of this section.

2. Is your pharmacy program included in the capitation rate (carved in)?

Yes                       No                       Partial

If "partial," please specify the drug categories that are carved out.

- Selected HIV/AIDS treatment drugs;
- Selected alcohol and heroin detoxification and dependency treatment drugs;
- Selected coagulation factors; and
- Selected drugs used to treat psychiatric conditions

3. Does the state set requirements for the MCO's pharmacy benefit (e.g. same PDL, same ProDUR/RetroDUR)?

Yes                       No

If "Yes," do please check all requirements that apply below:

Formulary Reviews     Same PDL     Same ProDUR     Same RetroDUR

If "Yes," please briefly explain your policy:

Medi-Cal MCO's are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program.

If "No," do you plan to set standards in the future?

Yes                       No

4. Does the state require the MCOs to monitor or report their DUR activities?

Yes                       No

If "Yes," please explain your review process.

MCOs submit DUR reports to both the Managed Care Division and the Audit & Investigations branch for review.

If "No" do you plan to develop a program to have MCOs report their DUR activities in the future?

Yes                       No

If "No," please explain.

5. Does all of the Medicaid MCOs in your state have a targeted intervention program (i.e. CMC/Lock In) for the misuse or abuse of controlled substances?

Yes

No

If "No," please explain.

Not a requirement of the MCO contracts.

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**XII. EXECUTIVE SUMMARY - Attachment 8 – Executive Summary**

**ATTACHMENT 1 – PHARMACY ORAL COUNSELING COMPLIANCE REPORT****Monitoring Pharmacy Compliance with OBRA 1990 DUR Requirements**

California pharmacy regulations require pharmacies to maintain patient medication profiles and counsel patients regarding their prescription medication before dispensing. Consultation provides the pharmacist with the opportunity to educate patients who present new prescriptions and protect them from potential problems associated with a new medication by discussing possible side effects, contraindications and the importance of following directions. Consultation also provides the pharmacist one more opportunity to prevent dispensing errors by inspecting the medication container's contents to assure that the proper drug is dispensed.

Compliance to these requirements is the responsibility of the California Department of Consumer Affairs, Board of Pharmacy, <http://www.pharmacy.ca.gov/publications/reports.shtml>.

As part of its ongoing activities, the California Board of Pharmacy investigates complaints involving care provided in pharmacies. The California Board of Pharmacy typically will inspect the pharmacy in question at the start of each complaint investigation. Other inspections the Board performs include but are not limited to initial licensure, changes in ownership, change in location or a remodel, or simply a random inspection. A major function of an inspector's activities during these inspections is education of licensees regarding compliance with laws and regulations.

When an inspector, who is a licensed pharmacist, visits a pharmacy to investigate a complaint or inspect a pharmacy, the inspector observes whether patient consultation is occurring and specifically notes the progress and components of the consultations; e.g., the temporal relationship between review of the patient profile and the consultation. Failure to consult or perform prospective drug utilization review prior to consultation results in a "correction ordered" and, possibly, a notice of violation. To ensure compliance, inspectors revisit pharmacies and follow up on correction notices. Violation notices usually result in the pharmacist, pharmacist-in-charge, and pharmacy management meeting with a subcommittee of the Board to discuss the violation.

The above referenced Board of Pharmacy regulations were determined previously by CMS to comply with the prospective DUR requirements of OBRA 90.

A specific report about compliance with oral counseling requirements is not available from the California State Board of Pharmacy. As described by this Board, they typically evaluate compliance whenever a pharmacy is brought to the Board's attention through issues of fraud or abuse or a complaint of any sort. Verification of oral counseling is contained within these reports (made to various state and federal agencies) and is not separated out.

The California Board of Pharmacy has a Patient's Bill of Rights ([http://www.pharmacy.ca.gov/consumers/bill\\_of\\_rights.shtml](http://www.pharmacy.ca.gov/consumers/bill_of_rights.shtml)) that specifically calls out

patient counseling under item 7, which states the following: “Patients have a right to competent counseling from the pharmacist to help them understand their medications and use them correctly.”

## **ATTACHMENT 2 – RETROSPECTIVE DUR EDUCATIONAL OUTREACH SUMMARY**

DHCS publishes and distributes Medi-Cal educational bulletins and alerts to all Medi-Cal providers. In addition, providers are identified for education on specific issues based on characteristics of their prescribing and receive intervention letters. Providers who receive an intervention letter are requested to complete and return a survey.

Medi-Cal educational bulletins are available to the public on the Medi-Cal DUR website at: <http://files.medi-cal.ca.gov/pubsdoco/dur/edarticles.asp>

The purpose of DUR educational bulletins and alerts is to increase Medi-Cal providers' understanding of current treatment guidelines and recommendations on drugs, disease states, and medical conditions. Utilization trends amongst FFS beneficiaries are presented to increase provider awareness. Specific recommendations are made with each article on how to improve the quality of care for Medi-Cal beneficiaries. Recommendations made to Medi-Cal providers through a total of nine educational bulletins and alerts distributed during FFY 2015 include the following:

1. Clinical Review: Use of Nicotine Replacement Therapy for Smoking Cessation—October 2014

Summary: This clinical review highlighted recommendations of the 2008 U.S Department of Health and Human Services, Public Health Service Clinical Practice Guideline, "Treating Tobacco Use and Dependence".

### Recommendations:

1. Health care providers should use brief intervention strategies to encourage patients to quit smoking
2. Health care providers should consistently identify and document current and past tobacco use or other nicotine use, including smokeless tobacco and electronic nicotine delivery systems (for example, e-cigarettes, e-hookahs).
3. Health care providers should encourage active tobacco users to quit at every patient encounter, as multiple attempts are often required to treat tobacco dependence.
4. Health care providers should recommend both counseling and medication to patients for best results unless contraindicated or not indicated, such as with light smokers (individuals smoking less than 10 cigarettes daily).
5. Health care providers should consider a medication regimen that includes combination NRT therapy (nicotine patch once daily plus short-acting NRT as needed). This regimen has been shown to be more effective at improving quit rates than NRT monotherapy.
6. Health care providers may promote the California Smokers' Helpline at 1-800-NO-BUTTS. Medi-Cal beneficiaries who call the California Smokers' Helpline are eligible for free telephone counseling and support. This program is led by the Medi-Cal Incentives to Quit Smoking (MIQS) project, funded by

the Centers for Medicare & Medicaid Services under the Affordable Care Act. More information may be found at: [www.nobutts.org/medi-cal/](http://www.nobutts.org/medi-cal/).

7. Health care providers should promote the Great American Smokeout, a social campaign by The American Cancer Society held each year. Printable Great American Smokeout tools and resources for the workplace, community and school can be found at [www.cancer.org/healthy/stayawayfromtobacco/greatamericansmokeout/tolsandresources/resources](http://www.cancer.org/healthy/stayawayfromtobacco/greatamericansmokeout/tolsandresources/resources).

2. Alert: Folic Acid Awareness Week is January 4<sup>th</sup>-10<sup>th</sup>, 2015 – December 2014

Summary: This alert promoted folic acid awareness week and reminded providers that both the United States Public Health Service and the Centers for Disease Control and Prevention (CDC) recommend that all women between 15 and 45 years of age should consume 0.4 mg folic acid daily.

Recommendations:

1. Health care providers should promote the use of folic acid. The National Birth Defects Prevention Network has updated promotional and patient educational materials on their website, which are available in both English and Spanish: [www.nbdpn.org/faaw2015.php](http://www.nbdpn.org/faaw2015.php).

3. Alert: Depression Among Perinatal Women is Overlooked and Undertreated – January 2015

Summary: This alert summarized a recent publication that showed perinatal women enrolled in the Medi-Cal fee-for-service program were less likely to be diagnosed with depression than non-pregnant women and less likely to receive treatment for depression than non-pregnant women. A link to an interview with the lead author was provided in the alert.

Recommendations:

1. Health care providers should screen for depression in all perinatal women and seek appropriate treatment options, as needed.

4. Improving the Quality of Care: Methotrexate use and Folate Supplementation - February 2015

Summary: This bulletin reviewed evidence promoting the concomitant use of folic acid with methotrexate for reducing side effects in patients with rheumatoid arthritis.

Recommendations:

1. Health care providers should recommend folate supplementation with the initiation of methotrexate therapy, in order to improve the chances of patient adherence to methotrexate treatment by mitigating some of the side effects that may be associated with methotrexate therapy.

2. Health care providers should be aware of the most common recommendations for folate supplementation. These include either 1 – 2 mg daily (except on the day of methotrexate administration) or 5 – 10 mg once weekly, preferably the day after methotrexate administration.
  3. Health care providers may consider sharing with patients a patient handout on methotrexate describing the side effect profile and potential benefits of folate supplementation. The handout is available on the ACR website at [http://www.rheumatology.org/Practice/Clinical/Patients/Medications/Methotrexate\\_\(Rheumatrex,\\_Trexall\)/](http://www.rheumatology.org/Practice/Clinical/Patients/Medications/Methotrexate_(Rheumatrex,_Trexall)/).
  4. Health care provider should review evidence-based treatment of RA, available through published clinical practice guidelines on the ACR website at: [http://www.rheumatology.org/Practice/Clinical/Guidelines/Rheumatoid\\_Arthritis\\_\(Members\\_Only\)/](http://www.rheumatology.org/Practice/Clinical/Guidelines/Rheumatoid_Arthritis_(Members_Only)/).
5. Drug Safety Communication: Varenicline and Alcohol Use – March 2015

Summary: This alert described the warning issued by the U.S. Food and Drug Administration (FDA) that varenicline can change the way people react to alcohol.

Recommendations:

1. Providers should inform their patients who are taking varenicline that they should decrease the amount of alcohol they drink until they become aware of how varenicline affects their ability to tolerate alcohol.
6. Improving the Quality of Care: Antipsychotic Use in Children and Adolescents – March 2015

Summary: This bulletin reviewed FDA-approved indications for children and adolescents and presented Medi-Cal fee-for-service data on the 2015 HEDIS measures for safe and judicious use of antipsychotic medications in children and adolescents. Recent changes to Medi-Cal policy were also described, and resource links were provided to help providers navigate these policy changes.

Recommendations:

1. Health care providers should utilize psychosocial care, which includes behavioral interventions, psychological therapies, and skills training, among others, as the recommended first-line treatment option for children and adolescents diagnosed with nonpsychotic conditions such as attention-deficit disorder and disruptive behaviors.
2. Prior to the initiation of treatment with antipsychotic medication, health care provider should obtain a personal and family history of diabetes and hyperlipidemia, seizures and cardiac abnormalities, as well as any family history of previous response or adverse events associated with antipsychotic medication.

3. Health care providers should utilize antipsychotic medications as part of a comprehensive, multi-modal plan for coordinated treatment that includes psychosocial care.
  4. Antipsychotic dosing should follow the “start low and go slow” approach and seek to find the lowest effective dose. Determination of an appropriate target dose should follow both the current scientific literature and the clinical response of the patient, while also monitoring the patient for side effects and tolerability. Multiple clinical guidelines suggest that higher than approved dosages of antipsychotic medications should be avoided.
  5. Health care providers should periodically review the ongoing need for continued therapy with antipsychotic medications.
  6. Health care providers should monitor BMI, blood pressure, fasting blood glucose, and fasting lipid profiles according to the recommendations found in the consensus statement put forth by the American Diabetes Association and the American Psychiatric Association.
7. Drug Safety Communication: NSAIDs Increase Chance of Heart Attack or Stroke – August 2015

Summary: This alert summarized an announcement by the FDA that they would be strengthening an existing label warning that NSAIDs increase the chance of a heart attack or stroke.

Recommendations:

1. Health care providers should advise patients taking NSAIDs to seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath or trouble breathing, weakness in one part or side of their body, or slurred speech.
8. 2015 Immunization Updates: Influenza, HPV, MenB, PVC13 and SB 277 – September 2015

Summary: This educational bulletin is an annual publication provided by the DUR program to provide updates on immunization guidelines, products, policy and/or research each year. Links to recommended immunization schedules for 2015 in the United States are provided. The summary for 2015 included updates for influenza, HPV, MenB, PVC13, and a summary of a new California law that eliminates most vaccine exemptions for children entering school or daycare facilities.

Recommendations:

1. Health care providers should continue to recommend annual influenza vaccine for all patients 6 months of age and older who do not have contraindications.
2. Routine HPV vaccinations should be initiated at 11 or 12 years of age, although the series may be initiated as early as 9 years of age in children and youth with any history of sexual abuse or assault.

3. MenB vaccines should be given to persons 10 years of age and older who are at increased risk for MenB.
  4. Health care providers should recommend routine use of 13-valent pneumococcal conjugate vaccine (PCV13) among all adults 65 years of age and older.
  5. Health care providers should inform parents or guardians of students in any school or child care facility, whether public or private, that they will no longer be allowed to submit a personal beliefs exemption to a currently-required vaccine.
9. Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse – September 2015

Summary: This educational bulletin described the morphine equivalent daily dose (MEDD) and how it can help providers identify potential dose-related risk for prescription opioid overdose. The bulletin also includes links to resources for providers and summarizes best practices for responsible opioid prescribing.

Recommendations:

1. Health care providers should weigh the benefits and risks of opioid therapy, especially for opioid therapy when alternative treatments are ineffective.
2. Health care providers should discuss with patients the risks and benefits of pain treatment options, including those that do not involve prescription painkillers.
3. Health care providers should consider the best practices for responsible opioid prescribing, including:
  - Consulting California's Prescription Drug Monitoring Program (CURES) initially and at every subsequent visit
  - Conducting a physical exam, urine drug test, and document pain history prior to prescribing opioids
  - Screening for substance abuse, mental health problems, and other physical conditions that are contraindicated for opioid use
  - Advising against concomitant use of alcohol, sedatives, and hypnotics
  - Implementing pain treatment agreements
  - Prescribing the lowest effective dose of short-acting opioid producing analgesia and improved function (no more than 80 mg MEDD) in a limited supply with no refills
  - Regularly evaluating the role of opioid therapy beyond 3 months for non-cancer chronic pain
  - Using a tapering schedule (not abrupt cessation) to discontinue or reduce dose of opioids
  - Tracking and document levels of pain and function at every visit
  - Exercising vigilance at high doses
  - Considering the prescription of naloxone as a rescue medication in the event of a potentially life-threatening overdose and instruct caregivers on proper use and administration.

In addition, starting in FFY 2015, the Medi-Cal DUR program now sends educational intervention letters to selected providers and pharmacies on selected topics, in conjunction with the educational bulletins. The purpose of the educational intervention letters is to improve the quality of care of Medi-Cal beneficiaries. Providers are informed of the goal of intervention and receive educational materials along with suggested recommendations. A response survey is included with each letter to promote dialogue between the Medi-Cal DUR program and the providers and pharmacies. In FFY 2015, the following three mailings were sent to providers:

#### 1. Tramadol – October 2014

##### Objectives:

- To educate prescribers on the statistics regarding abuse and diversion of tramadol.
- To inform prescribers that tramadol is now a schedule IV controlled substance.
- To assess the feasibility and acceptability of a letter-writing intervention to health care providers in the Medi-Cal fee-for-service population.

Methods: The top 100 prescribers of tramadol to Medi-Cal FFS beneficiaries were identified and their National Provider Identifier (NPI) numbers were matched to the Medi-Cal provider file, in order to obtain mailing addresses. After matching, a total of 33 letters were sent to 32 providers (one provider had two mailing addresses listed). Each provider received a letter informing them of the assignment of tramadol as a schedule IV controlled substance. No protected health information was included.

Outcomes: While the overall response rate was low (9%), the responses collected via mail or telephone were unanimously positive, suggesting direct mailing of letters to providers is an acceptable mechanism for future DUR educational outreach efforts.

#### 2. Asthma – May 2015

##### Objectives:

- To improve the quality of asthma care in the Medi-Cal fee-for-service (FFS) population.
- To determine if including patient-specific profiles in an educational DUR outreach letter to providers results in improved outcomes over a generic mailing.

Methods: A total of 33 beneficiaries with asthma medications prescribed by 77 different providers met the inclusion/exclusion criteria (persistent asthma and a continuous asthma medication ratio  $<0.5$  during the measurement period). Two providers had more than one beneficiary in the cohort (one had two beneficiaries, and one had three beneficiaries), so in order to avoid these prescribers being

randomized into separate groups, they were randomized as a batch. The control group consisted of 17 beneficiaries and 42 prescribers, while the intervention group consisted of 16 beneficiaries and 35 prescribers. The control group received a letter and the Medi-Cal DUR educational bulletin on asthma care (published December 2013). The intervention group received detailed patient profiles, in addition to the letter and DUR educational bulletin.

Outcomes: A response rate of 24% in the intervention group vs 2% in the control group was noted. Additional outcomes will be evaluated at 90 days, 6 months and 12 months and presented to the DUR Board.

### 3. Antipsychotic Metabolic Monitoring in Children and Adolescents – August 2015

Objective:

- To improve metabolic monitoring rates among children and adolescents in the Medi-Cal fee-for-service population

Methods: A total of 548 children and adolescents met the inclusion/exclusion criteria ( $\geq 4$  paid claims for an antipsychotic medication and no paid claims for a HbA1C or LDL-C test during the measurement period), representing a total of 264 prescribers. Some prescribers had more than one address listed as their physical location, so a total of 274 prescriber letters were mailed. Each mailing included a letter with a summary of clinical recommendations, a list of identified patients, the Medi-Cal DUR educational bulletin on appropriate antipsychotic use among children and adolescents, and provider response surveys (one survey per patient).

Outcomes: 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. The primary outcome variable will be whether or not the beneficiary has a laboratory test for HbA1C/glucose and/or LDL-C/cholesterol within 90 days of the mailing of the intervention letter. The secondary outcome variable will be the percentage of patients with additional paid claims for antipsychotic medications within 6 months following the mailing of the intervention letter (stratified by laboratory monitoring status).

### **ATTACHMENT 3 – SUMMARY OF DUR BOARD ACTIVITIES**

The DUR Board met four times during FFY 2015. The Board members are listed below the summary.

#### **Prospective DUR Criteria Presented**

- HIV Antiretroviral Medications and Ingredient Duplication (ID): The Board reviewed HIV antiretroviral medications arriving on the market after the last review of the class, and recommended adding the following HIV antiretroviral therapy ingredients to the Target Drug List for Prospective DUR and activating the Ingredient Duplication (ID) alert for these drugs (in both their single and combination formulations): ATAZANAVIR, COBICISTAT, DARUNAVIR, and ELVITEGRAVIR.
- Acetaminophen and High Dose (HD)/Ingredient Duplication (ID): The Board reviewed an eleven-week summary of HD/ID alert data collected in test mode for acetaminophen-containing products. The summary found that of all paid claims for an acetaminophen-containing product, only 1.5% of these paid claims would have generated either an HD or ID alert. Given the low probability of alert fatigue and the high potential benefit to prevent risk of acetaminophen toxicity, the Board recommended moving HD/ID alerts for acetaminophen-containing products from test mode to active HD and ID alerts.
- Section 20 of the DUR Manual revisions: After a detailed review of discrepancies between what is posted in the Medi-Cal DUR Manual under “DUR: Prospective Drug Use Review - Section 20” and the actual programming in the current prospective DUR system, the Board recommended the following actions:
  - Turn on DA, MC, TD, and LR alerts for all ETANERCEPT GCNs
  - Turn on DA, MC, TD, ID, HD, and LD alerts for DICLOFENAC, as needed to make sure the alerts are consistent across all GCNs.
- Antidepressants: The Board reviewed prospective DUR alerts for all antidepressant drugs and addressed alert inconsistencies among existing and new drugs which had not been reviewed previously. The Board made recommendations to turn on prospective alerts in a consistent manner for each drug in the following therapeutic categories:
  - (a) SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS): Turn on TD, LR, AT, ID, PA, HD, and LD alerts.
  - (b) SEROTONIN-2 ANTAGONIST/REUPTAKE INHIBITORS (SARIS): Turn on TD, LR, AT, ID, PA, HD, and LD alerts.
  - (c) SEROTONIN-NOREPINEPHRINE REUPTAKE-INHIB (SNRIS): Turn on TD, LR, AT, ID, PA, HD, and LD alerts.
  - (d) SSRI & SEROTONIN RECEPTOR MODULATOR ANTIDEPRESSANTS: Turn on TD, LR, AT, ID, PA, HD, and LD alerts.
  - (e) TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL. RU-INHIB: Turn on MC, TD, LR, AT, ID, PA, HD, and LD alerts, with the exception for TRAZODONE, where LD and LR alerts will not be turned on as this drug is often used as a sleep aid and these alerts would not be valid under

those circumstances.

- Review of new Generic Code Number (GCN) sequence numbers: The DUR Board recommended turning on additional alerts for the following new GCNs that matched drugs appearing on the Medi-Cal target drug list for prospective DUR:
  1. GCN #072501: FLUPHENAZINE DECANOATE, Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
  2. GCNs #072587, #072589, #072677, and #072678: CANAGLIFLOZIN/METFORMIN HCL, Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
  3. GCN #072501: NALTREXONE HCL/BUPROPION HCL, Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
  4. GCNs #072943, #072944, #072943, #072944, and #070052: MORPHINE SULFATE, Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  5. GCNs #073029, #073030, and #073031: DAPAGLIFLOZIN/METFORMIN HCL, Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
  6. GCNs #073298 and #073299: ARIPIPRAZOLE, Drug-Disease (MC), Therapeutic Duplication (TD), Underutilization (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  7. GCNs #073302, #073303, #073304, #073305, #073306, and #073307: MORPHINE SULFATE/NALTREXONE, Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  8. GCN #073286: NAPROXEN NA-DIPHENHYDRAMIN, Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  9. GCN #072862: OXYCODONE, Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  10. GCN #073773: LEVONORGESTREL, Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  11. GCN #073806: ALBUTEROL SULFATE, Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  12. GCN #048908: DARBEPOETIN ALFA IN POLYSORBATE, Drug-Allergy (DA), Drug-Disease (MC), Underutilization (LR), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  13. GCNs #061443, #061444, #061445, #061446, #061447, #061448, and #061449: METHYLPHENIDATE HCL, High Dose (HD), Low Dose (LD)
  14. GCN #074064: TESTOSTERONE CYPIONATE, Additive Toxicity (AT), High Dose (HD), Low Dose (LD)

- 15.GCN #060913: FENTANYL HCL, Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- 16.GCN #074184: DOXYCYCLINE HYCLATE, Drug-Pregnancy (PG)

### **Retrospective DUR Criteria Presented**

- Metformin, ACE Inhibitors/ARBs, Statins, and Concomitant Use of Antipsychotics: Second-generation antipsychotics widely used today have been associated with significant weight gain, hyperglycemia, and increases in plasma lipid levels. Weight gain can occur in as many as 50% of patients taking atypical antipsychotics. Concomitant use of any statins, ACE inhibitors, ARBs, and/or metformin in the Medical fee-for-service population with at least one paid claim for an atypical antipsychotic medication was 37% overall. Values ranged from concomitant use of ARBs (5%) to concomitant use of statins (24%). The Board recommended a DUR bulletin to educate providers on the appropriate prescribing of antipsychotic medications in adults. The proposed bulletin will:
  - Evaluate whether the use of second-generation antipsychotic medication is for FDA-approved indications
  - Determine prevalence of co-morbid medical conditions, including diabetes, cardiovascular disease, and others
  - Evaluate concomitant use of statins, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blocker (ARB) drugs, and metformin, stratified by second-generation antipsychotic monotherapy or polypharmacy
  - Evaluate annual metabolic monitoring rates among beneficiaries with continuous use of second-generation antipsychotic medications
- Benztropine Mesylate and Concomitant Use of Antipsychotics: Anticholinergic agents including benzotropine and trihexyphenidyl are often prescribed to prevent or treat antipsychotic-induced extrapyramidal symptoms (EPS), including tremor, rigidity, bradykinesia, and acute dystonia. However, the need for continued therapy with anticholinergics is frequently not reassessed and many patients remain on them for years. Prescribers may be reluctant to discontinue anticholinergics, even when patients are prescribed second- or third-generation antipsychotics, which are less likely than first-generation antipsychotics to induce EPS. The Board expressed concerns over therapeutic appropriateness and potential adverse effects from long-term use of anticholinergics, which may include cognitive impairment and worsening of tardive dyskinesia. The Board recommends writing a DUR bulletin to educate providers on appropriate prescribing of anticholinergic medications in patients initiating or maintaining treatment with antipsychotic medications. The proposed bulletin will:
  - Provide a summary of current treatment guidelines, including the factors that should be considered in decisions regarding the prophylactic use of anticholinergic medications in acute-phase treatment
- Narcotic analgesics: A review of opioid utilization was requested by the Board, to evaluate possible effects of DEA reclassification of tramadol and hydrocodone on July 2, 2014, and October 6, 2014, respectively. While both monthly and quarterly

DUR reports show decreased utilization of both tramadol and hydrocodone medications since their corresponding scheduling change, it was not known if this decrease represented a shift to other opioids, or represented a true reduction in overall opioid utilization. The report showed that prior to rescheduling, the total paid claims for tramadol were almost double those of acetaminophen with codeine. However, by January 2015, five months after the rescheduling, claims for acetaminophen with codeine surpassed claims for tramadol. Between September 2014 and May 2015, total paid claims for hydrocodone with acetaminophen decreased by 33%. In addition, since February 2014, a slight increase in paid claims was noted for medications containing buprenorphine, along with a decrease of 46% in paid claims for methadone. Additional analysis showed a decrease in post-rescheduling utilization for tramadol and hydrocodone (by number of utilizing beneficiaries with claims for >120 dosage units) of 50.5%, and 61.0% respectively. The Board recommended continued monitoring of opioid utilization.

- Age ≥ 65 Years: Ongoing utilization reports showed that between March 2014 and May 2015, there was a 59% decrease in total utilizing beneficiaries aged 65 years and older in the Medi-Cal fee-for-service program. The Board had requested a formal review of this age group, along with a retrospective utilization review of drugs appearing on the 2012 AGE Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. An in-depth review of these beneficiaries found that almost all of the decrease occurred in counties currently enrolling beneficiaries in the Cal MediConnect program, a three-year collaboration between Medi-Cal and Medicare to promote coordinated health care delivery to seniors and people with disabilities who are dually-eligible for both of these public health insurance programs. The Board reviewed utilization of drugs appearing on the 2012 Beers Criteria during a one-year period (July 1, 2014 through June 30, 2015). The top drugs by total number of utilizing beneficiaries included diphenhydramine (n=1,633), ibuprofen (n=523), quetiapine (n=508), and insulin glargine (n=486). As of the September 2015 DUR Board meeting, it has not yet been determined whether the Cal MediConnect program will continue beyond the three-year pilot. Therefore, the Board recommended waiting for more information on the future of this program before pursuing additional analyses in this age group.

### **Provider-specific Interventions**

#### ***Educational articles and alerts:***

- Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse—September 2015
- Immunization Updates: Influenza, HPV, MenB, PVC13, and SB 277 – September 2015
- Drug Safety Communication: NSAIDs Increase Chance of Heart Attack or Stroke— August 2015
- Improving the Quality of Care: Antipsychotic Use in Children and Adolescents – March 2015
- Drug Safety Communication: Varenicline and Alcohol Use – March 2015

- Improving the Quality of Care: Methotrexate Use and Folate Supplementation – February 2015
- Alert: Depression Among Perinatal Women is Overlooked and Undertreated – January 2015
- Alert: Folic Acid Awareness Week is January 4<sup>th</sup>-10<sup>th</sup>, 2015 – December 2014
- Clinical Review: Use of Nicotine Replacement Therapy for Smoking Cessation – October 2014

***Provider intervention letters:***

- Tramadol – October 2014
- Asthma – May 2015
- Antipsychotic Metabolic Monitoring in Children and Adolescents – August 2015

**Ongoing DUR Board Projects**

The DUR Board goals for FFY 2015 were as follows:

1. Conduct systematic review to identify therapeutic drug categories and establish relative cost comparisons that also comply with contractual requirements for cost confidentiality
2. 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)
3. Recommend prospective DUR alerts system design as part of the new California Medication Management Information System
4. Expand and evaluate targeted DUR educational outreach to providers
5. Continue to collaborate with other agencies on related topics

The following are ongoing DUR Board projects:

- Relative Cost Comparison – The DUR Board is developing methodology to create a document containing the relative cost of select therapeutic classes based on publically available WAC prices. The purpose of this document is to give providers an easy tool to quickly assess relative costs of drug therapy for select disease states.
- Morphine Equivalent Daily Dose (MEDD) – The DUR Board continues to collaborate with other State agencies, including the California Medical Board, the Division of Worker's Compensation, and the State Board of Pharmacy to develop a cohesive policy regarding MEDD and prescription drug abuse.
- Intervention Work Group – Prior to FFY 2015, DUR interventions consisted of Medi-Cal educational bulletins and alerts. In FFY 2015, a work group consisting of representatives from DHCS, Xerox, and UCSF developed standard operating procedures for Retrospective DUR Educational Outreach Mailings, which will target individual providers and pharmacies, as needed, in order to improve quality of care. Appropriate quality control checkpoints and a procedure for collecting mailed responses were established. Both the feasibility and acceptability of the educational outreach letters to providers

and pharmacies were evaluated and results supported continuation of the program. The DUR Board is responsible for recommending criteria for the letters.

### **DUR Board Members**

The following members served on the DUR Board, either in part or for the entire duration, of FFY 2015:

<b>Member</b>	<b>Specialty/Affiliation</b>
Andrew L. Wong, M.D. Chair	Chief of Rheumatology Olive View-University of California, Los Angeles - Medical Center Professor of Clinical Medicine University of California, Los Angeles – David Geffen School of Medicine Los Angeles, California
Robert Mowers, Pharm.D. Vice Chair	Coordinator, Managed Care Pharmacy Services Department of Pharmacy Services University of California, Davis – Health System Sacramento, California
Marilyn Stebbins, Pharm.D.	Professor of Clinical Pharmacy UCSF School of Pharmacy San Francisco, California
Timothy E. Albertson, M.D., Ph.D.	Chair, Department of Internal Medicine, Division of Pulmonary and Critical Care Medicine and Professor of Medicine and Pharmacology, UC Davis Medical Center, Sacramento, California
Patrick Finley, Pharm.D.	Clinical Professor UCSF School of Pharmacy San Francisco, California
Janeen G. McBride, Pharm.D.	Vice President MedImpact Healthcare Systems, Inc. San Diego, California
Randall S. Stafford, M.D., Ph.D.	Director, Program on Prevention Outcomes and Practices, Stanford Prevention Research Center, and Professor of Medicine, Stanford University School of Medicine Palo Alto, California

## **ATTACHMENT 4 - GENERIC DRUG SUBSTITUTION POLICIES**

Among possible factors contributing to the Medi-Cal fee-for-service generic utilization percentage, the most impactful are the following: 1) supplemental rebate contracts with manufacturers; 2) carve-out drugs; and 3) generic drug pricing policies.

### **1) Restrictions to the Medi-Cal List of Contract Drugs**

The Medi-Cal Drug Rebate program negotiates supplemental rebate contracts with pharmaceutical manufacturers and collects rebates greater than rebates obtainable through federal contracts alone. As a result, the net cost to the State for some brand name drugs can be lower than the therapeutically equivalent generic drug. In some cases, contracted drugs are payable at the point of service, while their generic equivalents require prior authorization. On the Medi-Cal List of Contract Drugs, these drugs can be identified through restrictions to the NDC labeler code. The current Medi-Cal List of Contract Drugs is available here:

[http://files.medi-cal.ca.gov/pubsdoco/manual/man\\_query.asp?wSearch=%28%23filename+drugscdl%2A%2Edoc+OR+%23filename+drugscdl%2A%2Ezip%29&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contract+Drugs+List&wPath=N](http://files.medi-cal.ca.gov/pubsdoco/manual/man_query.asp?wSearch=%28%23filename+drugscdl%2A%2Edoc+OR+%23filename+drugscdl%2A%2Ezip%29&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contract+Drugs+List&wPath=N).

### **2) Carve-out Pharmacy Benefits**

The Medi-Cal fee-for-service program pays for certain carved-out therapeutic classes of drugs for beneficiaries in both the Medi-Cal fee-for-service program and the Medi-Cal managed care program. Most notably, this applies to selected psychiatric drugs, alcohol and heroin detoxification and dependency treatment drugs, coagulation factors, and drugs used in treatment of Human Immunodeficiency Virus (HIV) and AIDS. These classes of drugs are largely single-source innovator products and consistently account for a large portion of Medi-Cal drug benefit expenditures in the Medi-Cal fee-for-service population. For a complete description of the carved-out drugs, please see:

[https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcptwoplan\\_z01.doc](https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcptwoplan_z01.doc).

### **3) Policies encouraging generic equivalent substitution for drugs dispensed through the Medi-Cal program.**

In cases where generic drugs are more cost-effective, Medi-Cal encourages use of generic drugs. The providers, to the extent permitted by law, shall dispense the lowest cost drug product within the generic drug type in stock, which meets the medical needs of the beneficiary.

#### **California Business and Professions Code Section 4073 states:**

(a) "A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients

of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.”

(b) “In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) “Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b)...In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist...”

**The following policies affect generic utilization rate by establishing reimbursement rates for drugs dispensed through the Medi-Cal program:**

Reimbursement for any legend and non-legend drug covered under the Medi-Cal program is the lowest of:

- Maximum Allowable Ingredient Cost (MAIC) plus current professional fee
- Federal Upper Limit (FUL) plus current professional fees
- Estimated Acquisition Cost (EAC) plus current professional fees
- Charge to the general public

Among these, whenever available, MAIC\* and FUL\*\* promote the use of generic equivalents unless restricted on the Contract Drug List. The rates established by MAIC or FUL are generally much lower than the cost of branded products, which discourages providers from filling prescriptions with name brand drugs. Full reimbursement of prescription ingredient cost requires use of a brand of a multiple source drug, which costs no more than the program specified price limits. When medically necessary for a specific recipient, approval of reimbursement may be obtained for a product whose price exceeds the MAIC or FUL price limits by requesting authorization from a Medi-Cal consultant.

**\*The Maximum Allowable Ingredient Cost (MAIC)**

The Maximum Allowable Ingredient Cost (MAIC) program establishes maximum ingredient cost limits for generically equivalent drugs. Each cost limit is established only when there are three or more generically equivalent drugs available for purchase and dispensing by retail pharmacies within California.

**\*\*Federal Upper Limit (FUL)**

Federal Upper Limit (FUL) is an upper-limit of reimbursement for certain multiple source drugs established independently from the California MAIC Program by the United States Department of Health and Human Services (DHHS).

The federally required FUL is administered by the Medi-Cal program in a similar manner as the MAIC program. The major difference is that changes to the FUL list of drugs and respective price limits are issued periodically by DHHS and then implemented by Medi-Cal. When a drug is listed on both the MAIC and FUL price lists, the reimbursement rate is the lower of the MAIC or FUL.

## **ATTACHMENT 5 – COST SAVINGS/COST AVOIDANCE METHODOLOGY**

Prospective DUR alerts and educational bulletins provide health care providers and pharmacists with specific, focused, and comprehensive drug information. If DUR alerts and educational bulletins are reviewed as intended, then notification of a potential drug therapy problem through a DUR alert or the knowledge gained from educational bulletins will lead to appropriate action, including:

- Discontinuing unnecessary prescriptions
- Reducing quantities of medications prescribed
- Switching to safer drug therapies
- Adding a drug therapy recommended in evidence-based guidelines
- Appropriate monitoring of patients taking prescription drugs

The Medi-Cal DUR program has saved money by encouraging appropriate drug therapy in order to reduce total healthcare expenditures. Estimated prescription drug savings as a direct result of the prospective DUR system for the FFY 2015 are shown in Table 1.

**Table 1. Prospective DUR Cost-Savings for Federal Fiscal Year (FFY) 2015.**

<b>Prospective DUR alert</b>	<b>Total claims cancelled or not overridden<sup>1</sup></b>	<b>Average reimbursement dollars paid to pharmacies per claim<sup>2</sup></b>	<b>Multiplier<sup>3</sup></b>	<b>Total estimated costs avoided through prospective DUR</b>
Over Utilization (Early Refill)	697,053	\$380	0.1	\$26,464,314
Therapeutic Duplication	199,439	\$333	0.8	\$53,117,786
Ingredient Duplication	186,394	\$417	0.8	\$62,248,140
Under Utilization (Late Refill)	112,569	\$382	0.8	\$34,389,379
High Dose	75,764	\$329	0.8	\$19,926,538
Low Dose	49,569	\$81	0.8	\$3,229,519
Clinical Misuse (Additive Toxicity)	46,467	\$280	0.8	\$10,414,928
Drug-Pregnancy	35,247	\$21	0.8	\$597,507
Drug-Drug Interaction	14,479	\$573	0.8	\$6,632,888
Drug-Disease Contraindication	6,224	\$93	0.8	\$461,273
Drug Allergy	490	\$85	0.8	\$33,159
Drug Age	162	\$235	0.8	\$30,435
<b>TOTAL: All Alerts</b>	<b>1,423,857</b>	<b>\$333</b>		<b>\$217,545,867</b>

<sup>1</sup>Multiple alerts can be generated per claim, so there may be duplicate alerts cancelled or overridden.

<sup>2</sup>Average reimbursement dollars paid to pharmacies per claim was calculated for each alert by looking at the total number of paid claims (including overrides) and total reimbursement dollars paid to pharmacies per claim (does not include adjustment for any rebates) for all drugs that generated that particular alert in FFY 2015.

<sup>3</sup>The use of this multiplier allows for an adjustment of estimated costs using a conservative estimate that 90% of early refill claims are resubmitted and paid and that 20% of the remaining alerts are duplicate alerts for the same claim.

## **ATTACHMENT 6 – INNOVATIVE PRACTICES**

The Medi-Cal DUR Program plays an integral role in the Department of Health Care Services' Strategy for Quality Improvement in Healthcare initiative. The following areas aimed to improve patient safety are directly linked to the activities of the DUR Program:

**1. Improve psychotropic medication use for children and youth in foster care:**

In collaboration with the California Department of Social Services and the Department of Health Care Services, the DUR Board aims to improve safe and appropriate prescribing and monitoring of psychotropic medication use for all children and adolescents, including those in foster care. The DUR Board advises and provides recommendations regarding draft guidelines for improving oversight and monitoring of psychotropic medication use for children and youth in foster care and optimal prescribing standards to engage prescribers to use minimum number of psychotropic medications, at the lowest appropriate dosage and at the appropriate age.

A DUR educational bulletin entitled, "*Improving the Quality of Care: Antipsychotic Use in Children and Adolescents*", was developed in collaboration with the Foster Care Quality Improvement Project Clinical Workgroup. In addition to reviewing current evidence on appropriate use of psychotropic medications in children and adolescents, the educational bulletin reviewed a policy change to require an approved *Treatment Authorization Request* for any prescriptions for antipsychotic medications for the population 0 through 17 years of age. Links to additional resources for providers, including the FAQ document for the policy change, were provided in the bulletin.

In addition, DHCS and the DUR Board supported educational outreach to providers to improve metabolic monitoring rates among children and adolescents prescribed antipsychotic medication. Intervention letters were sent to all prescribers of antipsychotic medications to children and adolescents between 0 and 17 years of age who did not have a medical claim for metabolic monitoring for over one year.

- 2. Reduce opiate overdose:** Both independently and in collaboration with the Audits & Investigations Branch, the DUR Board continues to evaluate opioid pharmacy claims data in order to: 1) characterize the nature and magnitude of opioid use in the Medi-Cal fee-for-service population and 2) develop effective policies and programs to reduce the adverse impact of opioid abuse. For example, the DUR Board approved a plan to send out letters to the top

prescribers of tramadol in the Medi-Cal fee-for-service population, in order to advise them of the change in scheduling of tramadol to a schedule IV controlled substance. Letters were sent to the top prescribers in October 2014. All provider responses, which were collected via both mail and through telephone contact, were positive.

The Medi-Cal DUR Program also continues to collaborate with the California State Board of Pharmacy (BOP) and their Prescription Abuse Subcommittee in their mission to:

- promote the prevention and treatment of prescription drug abuse, particularly the abuse of controlled substances
- provide education to practitioners and the public regarding prescription drug misuse
- optimize the widespread use of tools such as Controlled Substance Utilization Review and Evaluation System (CURES)

One of the emerging QI focus areas is to reduce opiate-related morbidity and mortality. In FFY 2015, the DUR program focused on identifying a morphine equivalent daily dose (MEDD) and disseminating information to providers on how to use the MEDD to identify potential dose-related risk. Through this process, the DUR Program collaborated with other state agencies including the Medical Board of California, the California Board of Pharmacy, and the California Division of Workers Compensation, in order to coordinate recommendations and educate providers on Morphine Equivalent Daily Dose. An educational bulletin, "Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse" was published in September 2015. The DUR Board agreed that the DUR Program should develop a letter to be mailed to selected providers with patients on opiates exceeding a defined MEDD.

- 3. Data sharing efforts to improve coordination of care among children and youth in foster care:** The purpose of data sharing is to explore, identify and support effective strategies in overseeing and monitoring of medical care and interventions, including medication use that are provided to children and youth in the child welfare system.

The initial data sharing agreements were initiated between the Pharmacy Benefits Division of the Department of Health Care Services (DHCS) and the Child Welfare Services of the California Department of Social Services (CDSS). The two departments began sharing psychotropic medication data on January 1, 2014. Mental health data was added on later than year, on October 1, 2014.

In 2015, CDSS and DHCS began discussion to significantly expand the scope of the data shared with the county behavioral health services for counties directly involved in the treatment and caring of these children and youth. A global data agreement was initiated between the 58 county behavioral health services and CDSS. Prior to the global data sharing agreement, only the case ID was shared. The global data sharing agreement enables sharing of client-specific mental health services, prescription claims, eligibility, and payment data. Counties must enroll in order to receive data and by the end of FFY 2015 a total of eleven counties had opted into the program.

**4. Aligning DUR program with DHCS Quality Strategy to optimize program effectiveness:** In an effort to align DUR program with DHCS Quality Strategy, Medi-Cal DUR Program staff and board members actively participate in multi-disciplinary and/or interdepartmental quality improvement initiatives, including the following:

- a. Participation in state-wide multi-disciplinary quality improvement project (QIP)
- b. Development of state clinical guidelines and quality of care standards: The California Guidelines on Psychotropic Medication Use for Children and Youth in Foster Care
- c. Development of clinical performance measures for the state on psychotropic medication use in children
- d. Promoting Medi-Cal Incentives to Quit Smoking (MIQS).
- e. Participation in Million Hearts Campaign
- f. DUR board member also serves on Quality Improvement Project Expert Panel
- g. Presenting DUR educational bulletin findings at DHCS Learning Series

## **ATTACHMENT 8 – EXECUTIVE SUMMARY**

The purpose of Drug Utilization Review (DUR) is to improve the quality and cost-effectiveness of drug use by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. California's Medi-Cal DUR program is the responsibility of the Department of Health Care Services (DHCS), and includes prospective DUR reviews, retrospective DUR reviews, and educational interventions for providers.

During federal fiscal year (FFY) 2015, California's Medi-Cal DUR program maintained a DUR Board comprised of four pharmacists and three physicians, meeting OBRA 1990 requirements. The DUR Board held four meetings in FFY 2015, with each meeting divided up into two distinct sections: 1) old business and follow-ups; and 2) new business that included placeholders for updates from DHCS and the DUR Board, drug utilization reports, prospective and retrospective DUR reviews, and descriptions of educational bulletins and/or alerts.

The DUR Board is responsible for advising and making recommendations to DHCS for the Medi-Cal fee-for-service population. For FFY 2015 the DUR Board advised and made recommendations for: 1) prospective DUR criteria review and evaluation; 2) focused retrospective analyses of claims data in order to study drug use in the Medi-Cal fee-for-service population; and 3) the development and implementation of educational interventions to improve drug use in the Medi-Cal fee-for-service population.

Over the course of FFY 2015, the DUR Board reviewed prospective DUR criteria for 22 drugs and implemented new criteria for all 22 of those drugs. In addition, retrospective DUR criteria for ten drugs and three drug therapeutic categories were reviewed. Finally, nine educational bulletins and alerts were published on the Medi-Cal website in order to educate and inform Medi-Cal providers and beneficiaries on timely and relevant topics related to medication use and three educational mailings were sent to selected providers to improve the quality of care for Medi-Cal beneficiaries.

This Annual Report was prepared through a collaborative effort between the California Department of Health Care Services, the California Drug Use Review Board, Xerox State Healthcare, LLC (formerly known as ACS, Inc.), and the University of California, San Francisco.

**TABLE 1 – TOP DRUG CLAIMS DATA  
REVIEWED BY THE DUR BOARD**

Top 10 PA Requests by Drug Name	Top 10 PA Requests by Drug Class	Top 5 Claim Denial Reasons (i.e. QL, Early Refill, PA, Duplication)	Top 10 Drug Names by Amount Paid	% of Total Spent for Drugs by Amount Paid	Top 10 Drug Names by Claim Count	Drugs By Claim Count % of Total Claims
ARIPIPRAZOLE	SECOND GENERATION ANTI-PSYCHOTICS	Claim requires an approved Treatment Authorization Request (TAR) due to beneficiary age	ARIPIPRAZOLE	12.0%	QUETIAPINE FUMARATE	4.0%
RISPERIDONE	OPIOID ANALGESICS AND COMBINATIONS	Claim requires an approved TAR due to exceeding quantity limits, days supply, and/or frequency	QUETIAPINE FUMARATE	8.0%	ASPIRIN	3.3%
HYDROCODONE/ACETAMINOPHEN	CNS STIMULANTS	Claim requires an approved TAR because claim exceeds the 6 prescription limit	OLANZAPINE	6.4%	IBUPROFEN	3.2%
QUETIAPINE FUMARATE	ANTI-DEPRESSANTS	Claim requires an approved TAR because beneficiary does not have the appropriate documented diagnosis on file for this drug	EMTRICITABIN E/TENOFOVIR	3.2%	ARIPIPRAZOLE	3.1%
PALIPERIDONE PALMITATE	BENZO-DIAZEPINES	Duplicate claim	LURASIDONE HCL	3.0%	RISPERIDONE	2.8%
ASPIRIN	PROTON PUMP INHIBITORS	XXXXXXX	EFAVIRENZ/EMTRICITAB/TENOFOVIR	2.4%	DOCUSATE SODIUM	2.2%
BUPRENORPHINE	SALICYLATES	XXXXXXX	ELVITEGR/COBICIST/EMTRIC/TENOF	2.4%	OLANZAPINE	2.1%
METHYL-PHENIDATE HCL	FIRST GENERATION ANTI-PSYCHOTICS	XXXXXXX	PALIPERIDONE PALMITATE	2.2%	LORATADINE	1.9%
LORAZEPAM	OPIOID AGONIST-ANTAGONIST FOR OPIOID DEPENDENCE	XXXXXXX	ZIPRASIDONE HCL	1.9%	ALBUTEROL SULFATE	1.8%
DEXTRO-AMPHETAMINE/AMPHETAMINE	BRONCHO-DILATORS	XXXXXXX	DARUNAVIR ETHANOLATE	1.5%	BENZ-TROPINE MESYLATE	1.8%

**TABLE 2 - GENERIC UTILIZATION DATA**

Single-Source (S) Drugs		Non-Innovator (N) Drugs		Innovator Multi-Source (I) Drugs	
Total Number of Claims	Total Reimbursement Amount Less Co-Pay	Total Number of Claims	Total Reimbursement Amount Less Co-Pay	Total Number of Claims	Total Reimbursement Amount Less Co-Pay
2,161,674	\$2,067,314,207	8,912,490	\$335,642,597	2,138,644	\$1,124,547,238

**KEY:**

**Single-Source (S)** - Drugs that have an FDA New Drug Application (NDA) approval for which there are no generic alternatives available on the market.

**Non-Innovator Multiple-Source (N)** - Drugs that have an FDA Abbreviated New Drug Application (ANDA) approval and for which there exists generic alternatives on the market.

**Innovator Multiple-Source (I)** - Drugs which have an NDA and no longer have patent exclusivity.

**QUARTERLY SUMMARY  
DRUG USE REVIEW (DUR) UTILIZATION REVIEW  
REPORT PERIOD: 2<sup>nd</sup> QUARTER 2016 (APRIL - JUNE 2016)**

**Executive Summary**

The DUR quarterly report provides information on both prospective and retrospective drug utilization for the Medi-Cal Fee-for-Service (FFS) program. For this quarterly report, the prospective and retrospective data cover the second quarter of 2016 (2016 Q2). All tables can be found in **Appendix A** and definitions of selected terms can be found in **Appendix B**.

***Prospective DUR***

As shown in **Table 1.1**, in 2016 Q2 overall drug claims decreased by 5% and total DUR alerts increased by 3% in comparison to the prior quarter (2016 Q1). Similarly, in comparison to the prior-year quarter (2015 Q2), overall drug claims decreased by 5% and total DUR alerts increased by 9%. In addition, total alert cancels (when the claim is cancelled after receiving an alert) increased by 4% from the prior quarter and increased by 21% in comparison to the prior-year quarter.

A comparison between 2016 Q2 and 2016 Q1 showed very little change among the top 10 drugs for each of the 12 prospective DUR alerts (**Tables 2.1-2.12**).

***Retrospective DUR***

A comparison of 2016 Q2 to the prior-year quarter showed a 5% decrease in total utilizing beneficiaries and a 7% decrease in total paid claims (**Table 3**). When overall utilization from 2016 Q1 was compared to the prior quarter there was also a decrease in total utilizing beneficiaries and total paid claims (both decreased by 6%). Of note, the total reimbursement paid to pharmacies decreased by double digits in comparison to the prior quarter, most likely due to labeler restrictions being changed or removed for several high-volume and/or high-cost drugs effective April 1, 2016, including QUETIAPINE, OLANZAPINE, and ATORVASTATIN CALCIUM.

In 2016 Q2, the 0-12 year age group posted double-digit across-the-board percentage decreases in total utilizing beneficiaries and total paid claims in comparison to both the prior quarter (**Table 4**) and the prior-year quarter.

As shown in **Table 5**, the following four 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: ANTIPSYCHOTIC, ATYPICAL, DOPAMINE, SEROTONIN ANTAGONIST, ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED, ANTIHYPERGLYCEMIC – HMG COA REDUCTASE INHIBITORS and ANTIHYPERGLYCEMIC, BIGUANIDE TYPE.

Similar findings can be seen in **Table 6**, where the following five drugs 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: QUETIAPINE FUMARATE, ARIPIPRAZOLE, METFORMIN HCL, OLANZAPINE, and ATORVASTATIN CALCIUM.

**Appendix A: Prospective and Retrospective DUR Tables**

**Tables 1.1-1.2. Summary of Prospective DUR Alert Transactions.**

**Table 1.1** provides summary level data (by volume) on pharmacy claims and DUR alert activities, including data and percent change from the prior quarter. Alerts are generated after adjudication of drug claims which exceed or otherwise fall outside of certain prescribed parameters. Please see **Appendix B** for definitions of terms used in this DUR report.

<b>Category</b>	<b>Current Quarter 2016 Q2 (Apr – Jun 2016)</b>	<b>Prior Quarter 2016 Q1 (Jan – Mar 2016)</b>	<b>% Change from <i>Prior</i> Quarter</b>	<b>Prior-Year Quarter 2015 Q2 (Apr – Jun 2015)</b>	<b>% Change from <i>Prior-Year</i> Quarter</b>
Drug Claims	8,833,238	9,320,333	<b>-5.2%</b>	9,268,586	<b>-4.7%</b>
DUR Drug Claims	4,548,064	4,764,062	<b>-4.5%</b>	4,729,831	<b>-3.8%</b>
Total Alerts	1,098,094	1,068,799	<b>2.7%</b>	1,009,315	<b>8.8%</b>
Total Alert Overrides	638,792	626,134	<b>2.0%</b>	577,796	<b>10.6%</b>
Total Alert Cancels	292	281	<b>3.9%</b>	242	<b>20.7%</b>

Note: Drug claims receiving multiple alerts can be adjudicated by pharmacists by responding to only one conflict code, followed by an intervention code and outcome code. The remaining alerts on the claim cannot be tracked as they are overridden by the pharmacist’s response to a single alert. For example, a single claim can generate up to eight different alerts, but the pharmacist can override all eight alerts by choosing to override only one alert. In addition, the number of cancelled alerts may be underrepresented due to the system’s inability to capture claims that were not adjudicated.

**Table 1.2** provides a summary of the number of drug claims and alerts generated for each therapeutic problem type (sorted by alert frequency). Total alerts not adjudicated may be overrepresented, as claims with multiple alerts that have been adjudicated under one alert will show up as not adjudicated for the remaining alerts.

<b>Therapeutic Problem Type</b>	<b>Total Alerts</b>	<b>Total Alert Overrides</b>	<b>% Alert Overrides</b>	<b>Total Alert Cancels</b>	<b>% Alert Cancels</b>	<b>Total Alerts Not Adjudicated</b>	<b>% Alerts Not Adjudicated</b>
Early Refill (ER)	337,664	102,626	30.4%	113	0.0%	234,925	69.6%
Ingredient Duplication (ID)	237,152	165,281	69.7%	45	0.0%	71,826	30.3%
Therapeutic Duplication (TD)	208,491	147,462	70.7%	47	0.0%	60,982	29.2%
Late Refill (LR)	133,380	100,289	75.2%	17	0.0%	33,074	24.8%
Total High Dose (HD)	62,117	36,904	59.4%	10	0.0%	25,203	40.6%
Additive Toxicity (AT)	45,533	35,899	78.8%	24	0.1%	9,610	21.1%
Total Low Dose (LD)	29,657	18,523	62.5%	4	0.0%	11,130	37.5%
Drug-Pregnancy (PG)	27,690	19,881	71.8%	6	0.0%	7,803	28.2%
Drug-Drug (DD)	12,365	9,145	74.0%	2	0.0%	3,218	26.0%
Drug-Disease (MC)	3,669	2,573	70.1%	0	0.0%	1,096	29.9%
Drug-Allergy (DA)	287	149	51.9%	0	0.0%	138	48.1%
Drug-Age (PA)	89	60	67.4%	0	0.0%	29	32.6%

**Tables 2.1-2.12. Prospective DUR Alert Transactions by Therapeutic Problem Type.**

Each of the following tables provides greater detail of each of the 12 DUR alerts with the top 10 drugs generating each respective alert. For each of the top 10 drugs, data are provided for the total number of adjudicated alerts, alert overrides, alert cancels, paid claims, and the percentage of paid claims with alert overrides. **Tables are listed in order of DUR alert priority, which is determined by the DUR Board.**

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	PHENYTOIN SODIUM EXTENDED	113	113	0	3,007	3.8%
2	PHENYTOIN	79	79	0	1,143	6.9%
3	AMOXICILLIN	9	9	0	47,659	0.0%
4	IBUPROFEN	8	8	0	103,157	0.0%
5	OXYCODONE HCL/ACETAMINOPHEN	5	5	0	8,056	0.1%
6	SULFAMETHOXAZOLE/TRIMETHOPRIM	5	5	0	21,700	0.0%
7	SOMATROPIN	3	3	0	2,126	0.1%
8	HYDROCHLOROTHIAZIDE	2	2	0	19,574	0.0%
9	LORATADINE	2	2	0	55,879	0.0%
10	RISPERIDONE	2	2	0	88,957	0.0%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	IBUPROFEN	16,651	16,647	4	103,157	16.1%
2	NORETHINDRONE	3,472	3,470	2	9,437	36.8%
3	ASPIRIN	653	653	0	78,870	0.8%
4	SULFAMETHOXAZOLE/TRIMETHOPRIM	615	615	0	21,700	2.8%
5	NAPROXEN	382	382	0	15,457	2.5%
6	DOXYCYCLINE HYCLATE	347	347	0	5,821	6.0%
7	MISOPROSTOL	320	320	0	808	39.6%
8	LORAZEPAM	239	239	0	13,847	1.7%
9	LISINAPRIL	172	172	0	39,241	0.4%
10	FLUCONAZOLE	137	137	0	16,268	0.8%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	POTASSIUM CHLORIDE	813	812	1	4,483	18.1%
2	METFORMIN HCL	695	695	0	47,511	1.5%
3	HALOPERIDOL	447	447	0	21,543	2.1%
4	METOPROLOL TARTRATE	104	104	0	10,866	1.0%
5	CARBAMAZEPINE	102	102	0	4,388	2.3%
6	HALOPERIDOL DECANOATE	73	73	0	4,125	1.8%
7	ATENOLOL	66	66	0	8,816	0.7%
8	METOPROLOL SUCCINATE	63	63	0	6,510	1.0%
9	PROPRANOLOL HCL	61	61	0	5,122	1.2%
10	DILTIAZEM HCL	60	60	0	2,027	3.0%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	GEMFIBROZIL	774	774	0	3,827	20.2%
2	SIMVASTATIN	698	697	1	17,686	3.9%
3	ATORVASTATIN CALCIUM	504	504	0	27,524	1.8%
4	ELVITEG/COBI/EMTRIC/TENOFO ALA	440	440	0	5,070	8.7%
5	AMLODIPINE BESYLATE	415	415	0	27,244	1.5%
6	METOCLOPRAMIDE HCL	391	391	0	6,187	6.3%
7	ZIPRASIDONE HCL	275	275	0	20,569	1.3%
8	DARUNAVIR ETHANOLATE	252	252	0	7,890	3.2%
9	ELVITEGR/COBICIST/EMTRIC/TENOF	197	197	0	6,208	3.2%
10	CHLORPROMAZINE HCL	170	169	1	6,285	2.7%

**Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2016 Q2**

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	29,192	29,186	6	138,290	21.1%
2	OLANZAPINE	19,416	19,414	2	73,173	26.5%
3	RISPERIDONE	15,555	15,548	7	88,957	17.5%
4	LURASIDONE HCL	9,405	9,404	1	35,551	26.5%
5	ZIPRASIDONE HCL	6,772	6,772	0	20,569	32.9%
6	TRAZODONE HCL	6,528	6,528	0	13,539	48.2%
7	CLOZAPINE	6,193	6,179	14	18,548	33.3%
8	PALIPERIDONE PALMITATE	5,315	5,315	0	14,858	35.8%
9	ALBUTEROL SULFATE	5,186	5,185	1	51,293	10.1%
10	BUPROPION HCL	4,757	4,757	0	7,684	61.9%

**Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2016 Q2**

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	11,481	11,475	6	138,290	8.3%
2	ARIPIPIRAZOLE	7,411	7,408	3	104,269	7.1%
3	OLANZAPINE	6,672	6,667	5	73,173	9.1%
4	RISPERIDONE	5,531	5,529	2	88,957	6.2%
5	BENZTROPINE MESYLATE	4,200	4,199	1	58,198	7.2%
6	LITHIUM CARBONATE	2,778	2,778	0	29,856	9.3%
7	ASPIRIN	2,380	2,379	1	78,870	3.0%
8	METFORMIN HCL	2,361	2,361	0	47,511	5.0%
9	ZIPRASIDONE HCL	2,171	2,171	0	20,569	10.6%
10	LEVETIRACETAM	1,906	1,905	1	18,471	10.3%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	20,896	20,893	3	138,290	15.1%
2	ARIPIPIRAZOLE	18,803	18,802	1	104,269	18.0%
3	RISPERIDONE	11,733	11,731	2	88,957	13.2%
4	OLANZAPINE	10,784	10,783	1	73,173	14.7%
5	BENZTROPINE MESYLATE	7,001	7,001	0	58,198	12.0%
6	LURASIDONE HCL	5,201	5,201	0	35,551	14.6%
7	LITHIUM CARBONATE	4,677	4,677	0	29,856	15.7%
8	ATORVASTATIN CALCIUM	3,568	3,568	0	27,524	13.0%
9	LEVOTHYROXINE SODIUM	3,411	3,408	3	31,262	10.9%
10	ZIPRASIDONE HCL	3,365	3,365	0	20,569	16.4%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	2,382	2,381	1	138,290	1.7%
2	ARIPIPIRAZOLE	2,195	2,195	0	104,269	2.1%
3	CLONAZEPAM	1,830	1,827	3	10,103	18.1%
4	LITHIUM CARBONATE	1,646	1,646	0	29,856	5.5%
5	OLANZAPINE	1,363	1,363	0	73,173	1.9%
6	HALOPERIDOL	1,289	1,285	4	21,543	6.0%
7	ZOLPIDEM TARTRATE	1,000	1,000	0	6,204	16.1%
8	TRAZODONE HCL	862	861	1	13,539	6.4%
9	RISPERIDONE	790	790	0	88,957	0.9%
10	CHLORPROMAZINE HCL	550	550	0	6,285	8.8%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	33,788	33,784	4	138,290	24.4%
2	OLANZAPINE	17,672	17,670	2	73,173	24.1%
3	ARIPIPIRAZOLE	14,701	14,699	2	104,269	14.1%
4	RISPERIDONE	12,921	12,919	2	88,957	14.5%
5	CLOZAPINE	6,128	6,128	0	18,548	33.0%
6	ALBUTEROL SULFATE	5,961	5,960	1	51,293	11.6%
7	ZIPRASIDONE HCL	5,470	5,470	0	20,569	26.6%
8	LURASIDONE HCL	5,359	5,359	0	35,551	15.1%
9	HALOPERIDOL	3,895	3,895	0	21,543	18.1%
10	DIVALPROEX SODIUM	3,734	3,734	0	14,237	26.2%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	AMITRIPTYLINE HCL	22	22	0	4,487	0.5%
2	DOXEPIN HCL	22	22	0	519	4.2%
3	SIMVASTATIN	18	18	0	17,686	0.1%
4	OLANZAPINE	9	9	0	73,173	0.0%
5	HYDROCODONE/ACETAMINOPHEN	8	8	0	48,258	0.0%
6	SIROLIMUS	7	7	0	825	0.8%
7	LORATADINE	6	6	0	55,879	0.0%
8	BUDESONIDE	4	4	0	4,829	0.1%
9	ACETAMINOPHEN	3	3	0	25,893	0.0%
10	LEVETIRACETAM	3	3	0	18,471	0.0%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	OLANZAPINE	10,362	10,361	1	73,173	14.2%
2	HYDROCODONE/ACETAMINOPHEN	3,275	3,275	0	48,258	6.8%
3	RISPERIDONE	3,238	3,236	2	88,957	3.6%
4	QUETIAPINE FUMARATE	2,955	2,955	0	138,290	2.1%
5	GABAPENTIN	1,491	1,491	0	25,711	5.8%
6	IBUPROFEN	1,476	1,474	2	103,157	1.4%
7	ZIPRASIDONE HCL	1,206	1,206	0	20,569	5.9%
8	AMOXICILLIN	1,109	1,109	0	47,659	2.3%
9	ARIPIRAZOLE	1,101	1,101	0	104,269	1.1%
10	AMOXICILLIN/POTASSIUM CLAV	1,018	1,018	0	11,458	8.9%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	LITHIUM CARBONATE	5,312	5,311	1	29,856	17.8%
2	GABAPENTIN	2,224	2,224	0	25,711	8.6%
3	AZITHROMYCIN	831	831	0	27,292	3.0%
4	AMOXICILLIN	738	738	0	47,659	1.5%
5	DIVALPROEX SODIUM	730	730	0	14,237	5.1%
6	BUPROPION HCL	667	667	0	7,684	8.7%
7	CLONIDINE HCL	664	664	0	10,739	6.2%
8	ALBUTEROL SULFATE	663	663	0	51,293	1.3%
9	AMOXICILLIN/POTASSIUM CLAV	531	530	1	11,458	4.6%
10	CEPHALEXIN	518	518	0	30,498	1.7%

**Table 3. Summary of Medi-Cal FFS Pharmacy / Drug Utilization Measures.**

This table shows pharmacy utilization for the Medi-Cal FFS population, including the percent change from the prior quarter and prior-year quarter. Please note that all retrospective data tables exclude claims from beneficiaries in the Family Planning, Access, Care, and Treatment (Family PACT) program and the California Children's Services/ Genetically Handicapped Persons Program (CCS/GHPP) because they have different guidelines concerning access to prescription drugs than other Medi-Cal FFS beneficiaries.

<b>Table 3: Pharmacy Utilization Measures for the Medi-Cal FFS Population</b>					
<b>Category</b>	<b>Current Quarter 2016 Q2</b>	<b>Prior Quarter 2016 Q1</b>	<b>Prior-Year Quarter 2015 Q2</b>	<b>% Change from <u>Prior Quarter</u></b>	<b>% Change from <u>Prior-Year Quarter</u></b>
Total Eligible FFS Beneficiaries	2,697,522	2,826,539	2,712,739	-4.6%	-0.6%
Total Utilizing FFS Beneficiaries	818,051	865,726	857,331	-5.5%	-4.6%
Total Paid Rx Claims	2,853,608	3,021,024	3,052,409	-5.5%	-6.5%
Average Paid Rx Claims per Eligible FFS Beneficiary	1.06	1.07	1.19	-1.0%	-6.0%
Average Paid Rx Claims per Utilizing FFS Beneficiary	3.49	3.49	3.56	0.0%	-2.0%
Total Reimbursement Paid (\$) to Pharmacies	\$629,661,657	\$748,793,485	\$713,536,140	-15.9%	-11.8%
Average Reimbursement Paid (\$) per Eligible FFS Beneficiary	\$233.42	\$264.92	\$277.71	-11.9%	-11.3%
Average Reimbursement Paid (\$) per Utilizing FFS Beneficiary	\$769.71	\$864.93	\$832.28	-11.0%	-7.5%
Average Reimbursement Paid (\$) per Paid Rx Claim	\$220.65	\$247.86	\$233.76	-11.0%	-5.6%

**Table 4. Pharmacy Utilization by Age Group in the Medi-Cal FFS Population.**

This table presents pharmacy utilization data broken out by age group, including the percent change from the prior quarter and prior-year quarter.

<b>Table 4: Pharmacy Utilization by Age Group in the Medi-Cal FFS Population</b>						
<b>Age Group (years)</b>	<b>Current Quarter 2016 Q2 Total Paid Claims</b>	<b>% Change Total Paid Claims from <u>Prior Quarter</u></b>	<b>% Change Total Paid Claims from <u>Prior-Year Quarter</u></b>	<b>Current Quarter 2016 Q2 Total Utilizing Beneficiaries</b>	<b>% Change Total Utilizing Beneficiaries from <u>Prior Quarter</u></b>	<b>% Change Total Utilizing Beneficiaries from <u>Prior-Year Quarter</u></b>
0 – 12	259,151	-23.3%	-18.6%	109,809	-19.1%	-15.5%
13 – 18	137,924	-8.5%	-11.7%	43,056	-8.1%	-10.3%
19 – 39	862,273	-3.6%	-0.9%	271,439	-3.0%	2.1%
40 – 64	1,283,095	-2.5%	-5.5%	295,380	-1.9%	-0.8%
65+	293,163	-2.7%	-9.2%	90,911	-2.9%	-13.3%
Total*	2,853,608	-5.5%	-6.5%	818,051	-5.5%	-4.6%

\* Unknowns represent less than 1% of total

**Table 5. Top 20 Drug Therapeutic Categories in the Medi-Cal FFS Population.**

This table presents utilization of the top 20 drug therapeutic categories, by **percentage of utilizing beneficiaries with a paid claim**. The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2016 Q2 Total Paid Claims	% Change Total Paid Claims from <i>Prior Quarter</i>	% Change Total Paid Claims from <i>Prior-Year Quarter</i>	Current Quarter 2016 Q2 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Utilizing Beneficiaries with a Paid Claim from <i>Prior Quarter</i>	% Change Utilizing Beneficiaries with a Paid Claim from <i>Prior-Year Quarter</i>
1	1	ANTIPSYCHOTIC, ATYPICAL, DOPAMINE, SEROTONIN ANTAGONIST	402,433	1.2%	0.3%	137,795	16.8%	1.1%	1.1%
2	2	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	126,307	-12.9%	-1.6%	107,872	13.2%	-1.2%	0.4%
3	3	PENICILLINS	64,928	-26.7%	-15.5%	58,961	7.2%	-2.0%	-0.8%
4	4	ANALGESICS, NARCOTICS	83,974	-4.4%	-13.9%	56,709	6.9%	0.1%	-0.5%
5	5	ANALGESIC/ANTI-PYRETTICS, SALICYLATES	77,966	0.6%	-12.2%	51,220	6.3%	0.3%	-0.7%
6	7	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	105,977	1.9%	2.3%	46,064	5.6%	0.4%	0.4%
7	6	LAXATIVES AND CATHARTICS	58,221	-2.0%	-14.4%	38,909	4.8%	0.1%	-0.6%
8	8	ANTI-HISTAMINES - 2ND GENERATION	55,933	-2.2%	-11.6%	37,590	4.6%	0.0%	-0.5%
9	9	IRON REPLACEMENT	48,294	2.3%	-8.7%	36,841	4.5%	0.3%	-0.3%
10	11	ANTICONVULSANTS	93,915	-1.5%	-5.3%	35,927	4.4%	0.2%	0.0%
11	12	ANTI-HYPERTENSIVES, ACE INHIBITORS	53,418	-1.3%	-5.8%	34,436	4.2%	0.2%	0.0%
12	14	ANTI-HYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	53,526	4.6%	2.8%	33,942	4.1%	0.4%	0.3%
13	10	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	47,085	-29.9%	-16.6%	33,553	4.1%	-1.7%	-0.6%
14	16	ANTI-HYPERGLYCEMIC, BIGUANIDE TYPE	45,416	0.0%	1.5%	29,792	3.6%	0.2%	0.2%
15	13	PRENATAL VITAMIN PREPARATIONS	32,043	-6.8%	-17.8%	28,151	3.4%	-0.1%	-0.5%
16	19	CEPHALOSPORINS - 1ST GENERATION	28,864	-2.7%	-5.9%	27,153	3.3%	0.1%	0.0%
17	15	TOPICAL ANTI-INFLAMMATORY STEROIDAL	33,400	1.5%	-10.5%	27,106	3.3%	0.2%	-0.1%
18	18	ANTI-HISTAMINES - 1ST GENERATION	36,500	-4.5%	-11.3%	25,624	3.1%	0.0%	-0.2%
19	21	ANTI-PARKINSONISM DRUGS, ANTICHOLINERGIC	63,867	-0.1%	-2.7%	25,611	3.1%	0.2%	0.1%
20	22	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	45,611	2.0%	-3.6%	24,760	3.0%	0.2%	0.0%

**Table 6. Top 20 Drugs in the Medi-Cal FFS Population.**

This table presents utilization of the top 20 drugs, by **percentage of utilizing beneficiaries with a paid claim**. The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Utilization of drugs for Medi-Cal fee-for-service beneficiaries also includes carved-out drugs utilized by beneficiaries in Medi-Cal managed care plans. Carved-out drugs are listed below in bolded and italicized print.

**Table 6: Top 20 Drugs by *Percentage of Utilizing Beneficiaries with a Paid Claim***

Rank	Last Year Rank	Drug Description	Current Quarter 2016 Q2 Total Paid Claims	% Change Total Paid Claims from <i>Prior Quarter</i>	% Change Total Paid Claims from <i>Prior-Year Quarter</i>	Current Quarter 2016 Q2 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change of Utilizing Beneficiaries with a Paid Claim from <i>Prior Quarter</i>	% Change of Utilizing Beneficiaries with a Paid Claim from <i>Prior-Year Quarter</i>
1	1	IBUPROFEN	102,651	-15.3%	-4.7%	90,841	11.1%	-1.3%	0.0%
2	3	<b><i>QUETIAPINE FUMARATE</i></b>	<b>138,118</b>	1.2%	2.2%	<b>53,419</b>	<b>6.5%</b>	0.4%	0.5%
3	2	ASPIRIN	77,913	0.6%	-12.0%	51,179	6.3%	0.3%	-0.6%
4	5	<b><i>ARIPIRAZOLE</i></b>	<b>104,053</b>	1.2%	0.4%	<b>45,350</b>	<b>5.5%</b>	0.4%	0.3%
5	4	AMOXICILLIN	47,187	-27.9%	-15.2%	43,700	5.3%	-1.6%	-0.6%
6	6	HYDROCODONE/ ACETAMINOPHEN	47,665	-5.7%	-13.3%	38,514	4.7%	0.0%	-0.4%
7	8	LORATADINE	55,344	-2.2%	-11.5%	37,322	4.6%	0.0%	-0.5%
8	7	DOCUSATE SODIUM	54,580	-2.0%	-13.8%	37,258	4.6%	0.1%	-0.5%
9	10	FERROUS SULFATE	48,243	2.3%	-6.6%	36,818	4.5%	0.3%	-0.2%
10	11	<b><i>RISPERIDONE</i></b>	<b>88,213</b>	-1.5%	-7.4%	<b>35,824</b>	<b>4.4%</b>	0.2%	-0.1%
11	9	ALBUTEROL SULFATE	48,072	-31.8%	-18.2%	34,522	4.2%	-1.9%	-0.8%
12	13	METFORMIN HCL	45,416	0.0%	1.9%	29,792	3.6%	0.2%	0.3%
13	16	<b><i>OLANZAPINE</i></b>	<b>73,112</b>	2.1%	4.8%	<b>27,825</b>	<b>3.4%</b>	0.3%	0.4%
14	14	CEPHALEXIN	28,834	-2.6%	-5.5%	27,141	3.3%	0.1%	0.0%
15	17	LISINAPRIL	38,262	-0.9%	-1.9%	24,923	3.0%	0.1%	0.1%
16	12	ACETAMINOPHEN	25,338	-29.2%	-20.4%	23,767	2.9%	-0.9%	-0.5%
17	19	<b><i>BENZTROPINE MESYLATE</i></b>	<b>58,176</b>	0.0%	-1.5%	<b>23,459</b>	<b>2.9%</b>	0.2%	0.1%
18	18	FOLIC ACID	34,455	-1.1%	-10.4%	20,383	2.5%	0.1%	-0.3%
19	15	AZITHROMYCIN	21,511	-45.7%	-24.0%	20,085	2.5%	-1.8%	-0.6%
20	37	ATORVASTATIN CALCIUM	27,282	15.2%	27.0%	17,414	2.1%	0.4%	0.6%

## **APPENDIX B: Definition of terms.**

**Adjudicate:** To pay or deny drug claims after evaluating the claim for coverage requirements

**Average Reimbursement (\$):** A measure of the mean value of the reimbursement in dollars; the sum of the reimbursement divided by the number measured (in dollars).

**Beneficiary:** A person who has been determined eligible for Medi-Cal, as according to the California Code of Regulations 50024

**Eligible FFS beneficiary:** A Medi-Cal FFS beneficiary that qualifies for drug benefits

**Quarter:** One fourth,  $\frac{1}{4}$ , 25% or .25 of a year measured in months.

**Reimbursement:** The reimbursement paid to Medi-Cal pharmacy providers for legend and nonlegend drugs dispensed to Medi-Cal Fee-for-Service (FFS) beneficiaries. Reimbursement is determined in accordance with CA Welfare and Institutions Code Section 14105.45(b)(1).

**Drug therapeutic category:** Drug therapeutic categories are grouping of drugs at various hierarchy levels and characteristics that may be similar in chemical structure, pharmacological effect, clinical use, indications, and/or other characteristics of drug products.

**Utilizing FFS beneficiary:** A Medi-Cal beneficiary with at least one FFS prescription filled during the measurement period



## PHYSICIAN-ADMINISTERED DRUGS: 1<sup>st</sup> QUARTER 2016

Utilization of physician-administered drugs during the first quarter of 2016 (January – March 2016) is presented below, stratified by category. In order to show changes in utilization over time, **Table 1** shows the comparison to the prior quarter (2016 Q4) and **Table 2** shows the comparison to the prior-year quarter (2015 Q1).

<b>Table 1: 2016 Q1 Physician-Administered Drugs: Change from 2016 Q4 (one quarter)</b>						
Category	Total Utilizing Beneficiaries	% Change from 2016 Q4	Total Paid Claims	% Change from 2016 Q4	Total Reimbursement Dollars Paid	% Change from 2016 Q4
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	19,058	-35.8%	29,321	-20.6%	\$749,576	-29.9%
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	287,830	2.0%	674,447	1.3%	\$72,443,536	-0.1%
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	130,204	3.1%	267,058	-1.1%	\$3,038,791	-0.9%
<b>TOTAL</b>	<b>437,092</b>	<b>-0.3%</b>	<b>970,826</b>	<b>0.9%</b>	<b>\$76,231,903</b>	<b>-1.5%</b>

<b>Table 2: 2016 Q1 Physician-Administered Drugs: Change from 2015 Q1 (one year)</b>						
Category	Total Utilizing Beneficiaries	% Change from 2015 Q1	Total Paid Claims	% Change from 2015 Q1	Total Reimbursement Dollars Paid	% Change from 2015 Q1
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	19,058	-17.6%	29,321	-14.5%	\$749,576	-20.2%
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	287,830	-13.7%	674,447	-11.2%	\$72,443,536	-12.7%
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	130,204	-11.4%	267,058	-14.0%	\$3,038,791	-9.7%
<b>TOTAL</b>	<b>437,092</b>	<b>-13.2%</b>	<b>970,826</b>	<b>-11.3%</b>	<b>\$76,231,903</b>	<b>-12.1%</b>

The following three tables show the top 20 physician-administered drugs by total utilizing beneficiaries (**Table 3**), total reimbursement dollars paid (**Table 4**), and reimbursement paid per utilizing beneficiary (**Table 5**). Each table has the comparison to the prior quarter and the prior-year quarter, for reference. In addition, the prior-year ranking is given to show changes in utilization of a drug over time.

**Table 3: Top 20 Physician-Administered Drugs by Total Utilizing Beneficiaries**

Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q1 Total Utilizing Beneficiaries	% Change Total Utilizing Beneficiaries from 2016 Q4	% Change Total Utilizing Beneficiaries from 2015 Q1	2016 Q1 Total Reimbursement Dollars Paid	2016 Q1 Total Paid Claims
1	1	J3490	MEDROXYPROGES TERONE ACETATE	44,053	-0.4%	-9.4%	\$2,902,211	44,897
2	2	J3490	LEVONORGESTREL	31,218	1.4%	-14.7%	\$958,555	32,786
3	3	J3490	ULIPRISTAL ACETATE	24,126	-4.7%	-14.2%	\$744,176	25,341
4	4	S4993	LEVONORGESTREL -ETHIN ESTRADIOL	22,896	1.2%	-12.5%	\$2,782,952	23,328
5	5	J2405	ONDANSETRON HCL/PF	22,396	-3.4%	-13.4%	\$124,393	27,096
6	6	J1885	KETOROLAC TROMETHAMINE	19,049	2.9%	12.9%	\$117,560	20,914
7	7	X7700	0.9 % SODIUM CHLORIDE	14,817	0.6%	-2.1%	\$351,829	23,945
8	9	J2270	MORPHINE SULFATE	12,247	-6.5%	-11.0%	\$84,500	14,681
9	10	Z7610	ACETAMINOPHEN	11,668	24.3%	-8.2%	\$104,869	13,405
10	8	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	11,562	6.8%	-22.7%	\$1,336,735	11,867
11	11	J0696	CEFTRIAZONE SODIUM	11,211	8.8%	-10.8%	\$72,067	12,280
12	14	J7307	ETONOGESTREL	9,890	7.0%	-0.6%	\$7,167,937	9,890
13	12	Z7610	IBUPROFEN	9,607	10.7%	-9.3%	\$80,790	10,009
14	15	Q0144	AZITHROMYCIN	9,160	1.6%	-2.9%	\$81,304	9,533
15	17	J1100	DEXAMETHASONE SOD PHOSPHATE	8,567	6.4%	-2.3%	\$58,364	11,185
16	18	J3010	FENTANYL CITRATE/PF	7,544	0.8%	-10.6%	\$39,518	8,487
17	16	Z7610	HYDROCODONE/AC ETAMINOPHEN	7,530	1.1%	-16.1%	\$76,893	8,238
18	19	J1170	HYDROMORPHONE HCL	7,390	-8.1%	-10.1%	\$61,751	9,784
19	22	S0191	MISOPROSTOL	6,798	17.6%	0.7%	\$13,105	6,856
20	13	J7303	ETONOGESTREL/ETHINYL ESTRADIOL	6,695	-5.9%	-33.2%	\$1,190,481	6,747

**Table 4: Top 20 Physician-Administered Drugs by Total Reimbursement Dollars Paid**

Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q1 Total Reimbursement Dollars Paid	% Change Total Reimbursement Dollars from 2016 Q4	% Change Total Reimbursement Dollars from 2015 Q1	2016 Q1 Total Utilizing Beneficiaries	2016 Q1 Total Paid Claims
1	2	J7307	ETONOGESTREL	\$7,167,937	6.9%	14.3%	9,890	9,890
2	1	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	\$5,498,426	-5.4%	-42.6%	41	141
3	3	J7302	LEVONORGESTREL	\$3,932,925	3.7%	-11.5%	5,507	5,539
4	12	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	\$3,118,779	45.7%	33.4%	41	304
5	7	J3490	MEDROXYPROGESTERONE ACETATE	\$2,902,211	-0.4%	-5.5%	44,053	44,897
6	6	S4993	LEVONORGESTREL-ETHIN ESTRADIOL	\$2,782,952	3.0%	-12.0%	22,896	23,328
7	4	J9355	TRASTUZUMAB	\$2,553,283	-4.3%	-28.4%	292	973
8	5	90378	PALIVIZUMAB	\$2,440,339	68.4%	-26.5%	505	1,198
9	8	J7300	COPPER	\$2,249,943	-0.3%	-16.8%	3,459	3,484
10	10	Q4081	EPOETIN ALFA (100 UNITS ESRD)	\$2,195,619	1.0%	-8.3%	1,847	43,727
11	11	J7192	ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)	\$2,159,541	-5.6%	-9.3%	65	188
12	13	J1745	INFLIXIMAB	\$1,985,208	4.5%	2.3%	428	878
13	9	J2505	PEGFILGRASTIM	\$1,954,613	-13.1%	-25.3%	286	591
14	17	J7304	NORELGESTROMIN/ETHIN. ESTRADIOL	\$1,791,314	1.7%	19.1%	5,150	5,218
15	20	J1300	ECULIZUMAB	\$1,462,378	-7.7%	26.9%	21	127
16	16	J9035	BEVACIZUMAB	\$1,423,401	-2.0%	-17.0%	265	622
17	15	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	\$1,336,735	8.8%	-24.0%	11,562	11,867
18	14	J7303	ETONOGESTREL/ETHINYL ESTRADIOL	\$1,190,481	-10.1%	-35.1%	6,695	6,747
19	21	J0886	EPOETIN ALFA (1000 UNITS ESRD)	\$1,081,376	-7.6%	-4.6%	925	17,414
20	19	J9306	PERTUZUMAB	\$1,073,747	12.7%	-8.4%	106	740

**Table 5: Top 20 Physician-Administered Drugs by *Reimbursement Paid per Utilizing Beneficiary***

Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q1 Reimbursement Dollars Paid per Utilizing Beneficiary	% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2016 Q4	% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2015 Q1	2016 Q1 Total Reimbursement Dollars Paid	2016 Q1 Total Utilizing Beneficiaries
1	2	J1322	ELOSULFASE ALFA	\$149,951	-43.6%	78.9%	\$449,853	3
2	1	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	\$134,108	-10.0%	-37.7%	\$5,498,426	41
3	11	J7181	FACTOR XIII A-SUBUNIT,RECOMB (TRETEN®)	\$116,080	42.0%	21.6%	\$232,160	2
4	5	J7201	FACTOR IX REC, FC FUSION PROTN (ALPROLIX®)	\$115,561	-17.2%	68.4%	\$462,242	4
5	4	J1458	GALSULFASE	\$105,211	13.7%	6.1%	\$526,053	5
6	3	J7198	ANTI-INHIBITOR COAGULANT COMP. (FEIBA NF®)	\$102,386	-3.5%	-15.3%	\$1,023,857	10
7	6	J1743	IDURSULFASE	\$91,867	16.6%	-1.6%	\$734,935	8
8	27	J7185	ANTIHEMOPH.FVIII,B-DOMAIN DEL (XYNTHA®)	\$86,251	9.7%	332.7%	\$172,502	2
9	9	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	\$76,068	31.5%	-20.8%	\$3,118,779	41
10	13	Q9975	ANTIHEMOPH.FVIII REC,FC FUSION (ELOCTATE®)	\$69,819	20.3%	-2.7%	\$558,549	8
11	8	J1300	ECULIZUMAB	\$69,637	-7.7%	-1.8%	\$1,462,378	21
12	10	J0180	AGALSIDASE BETA	\$68,416	-19.0%	25.3%	\$273,665	4
13	15	J0221	ALGLUCOSIDASE ALFA	\$67,422	45.3%	-16.5%	\$202,265	3
14	16	J7190	ANTIHEMOPHILIC FACTOR, HUMAN (KOATE-DVI®)	\$48,600	-67.0%	204.7%	\$48,600	1
15	24	J1931	LARONIDASE	\$42,920	94.2%	-2.2%	\$85,840	2
16	7	J1786	IMIGLUCERASE	\$40,327	-0.4%	-48.0%	\$161,310	4
17	N/A	J3385	VELAGLUCERASE ALFA <sup>1</sup>	\$39,078	5.6%	N/A	\$39,078	1
18	14	J0840	ANTIVENIN,CROTALIDAE FAB(OVIN)	\$38,897	175.4%	-75.1%	\$77,794	2
19	20	J7192	ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)	\$33,224	10.4%	6.2%	\$2,159,541	65
20	N/A	J9315	ROMIDEPSIN <sup>1</sup>	\$30,586	138.9%	N/A	\$30,586	1

<sup>1</sup>In 2016 Q1, only one beneficiary had paid claims for this drug and in 2015 Q1 there were no beneficiaries with paid claims for this drug.



**PROSPECTIVE DUR REVIEW**

**DATE OF REVIEW:** August 16, 2016

**FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:**

- ANALGESIC, NON-SAL.- 1ST GENERATION ANTIHISTAMINE
- ANALGESIC/ANTIPIRETICS, NON-SALICYLATE
- ANALGESICS, NARCOTICS
- ANTIARRHYTHMICS
- ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS
- ANTICONVULSANTS
- ANTIHYPERGLYCEMIC, DPP-4 INHIBITOR & BIGUANIDE COMB
- ANTIVIRALS, HIV-SPEC, NUCLEOSIDE-NUCLEOTIDE ANALOG
- ANTIVIRALS, HIV-1 INTEGRASE STRAND TRANSFER INHIBTR
- SELECTIVE SEROTONIN 5-HT2A INVERSE AGONISTS (SSIA)
- NON-NARC ANTITUSS-1ST ANTIHIST-DECONG-ANALG-EXPECT
- NSAID & TOPICAL IRRITANT COUNTER-IRRITANT COMB.
- NSAIDS, CYCLOOXYGENASE-2(COX-2) SELECTIVE INHIBITOR
- TETRACYCLINES
- TOPICAL ANTI-INFLAMMATORY, NSAIDS

**DRUG PROBLEM TYPES:** Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Underutilization (LR), Additive Toxicity (AT), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)

**BACKGROUND:** Each week new Generic Code Number (GCN) sequence numbers are added. Prospective DUR alerts for Overutilization (ER) and Severity Level 1 Drug-Drug Interactions (DD) are automatically turned on for all new GCNs.

**ISSUES:** 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 alert profile for the new GCN. A list of new GCNs with alerts turned on other than ER and DD is provided to the DUR Board for review at each DUR Board meeting.

**Table 1. New GCNs for Existing DUR Target Drugs: Q2 2016 (04/01/16 – 06/30/16).**

Date	GCN	Drug Description	Additional Alerts Turned on
4/6/2016	075729	GABAPENTIN/LIDOCAINE/MENTHOL	DA, LR, ID, HD, LD
4/21/2016	068868	MORPHINE SULFATE/0.9% NACL/PF	DA, MC, TD, AT, ID, HD, LD
	068870		
	075812	EMTRICITABINE/TENOFOV ALAFENAM	ID
	071205	ACETAMINOPHEN	ID, HD
	075849	METHOTREXATE/PF	PG
	075850		
	075823	NAPROXEN/CAPSI/MENTHOL/ME-SAL	DA, PG, MC, TD, ID, HD, LD
075811	DICLOFEN SOD/KINESIOLOGY TAPE	DA, PG, MC, TD, ID, HD, LD	

4/28/2016	070009	FENTANYL CITRATE-0.9 % NACL/PF	DA, PG, MC, TD, ID, HD, LD
	075855	GABAPENTIN/CAPSI/ME-SAL/MENTH	DA, LR, ID, HD, LD
5/4/2016	075937	CELECOXIB/CAPSAICIN/MENTHOL	DA, PG, MC, TD, ID, HD, LD
	075893	DIPHENHYDRAM/PE/DM/ACETAMIN/GG	ID, HD
5/18/2016	076001	MORPHINE SULFATE	DA, MC, TD, AT, ID, HD, LD
	076031	OXYCODONE HCL	DA, MC, TD, AT, ID, HD, LD
	076032		
	076033		
	076034		
	076035		
	076023	ACETAMINOPHEN/ D-BROMPHENIRAMIN	ID, HD
	076018	CELECOXIB/LIDOCAINE/MENTHOL	DA, PG, MC, TD, ID, HD, LD
076025	PIMAVANSERIN TARTRATE	MC, TD, LR, AT, ID, HD	
5/25/2016	076097	EMTRICITABINE/TENOFOVIR	ID
	076101		
	076102		
6/8/2016	076131	DICLOFENAC/ME-SALIC/MENTH/CAMP	DA, PG, MC, TD, ID, HD, LD
	076079	DOXYCYCLINE MONOHYDRATE	PG
6/15/2016	076198	MORPHINE SULFATE/0.9% NACL/PF	DA, MC, TD, AT, ID, HD, LD
	076200		DA, MC, TD, AT, ID, HD, LD
6/22/2016	076221	FENTANYL CITRATE	DA, MC, TD, AT, ID, HD, LD
	076226	DOLUTEGRAVIR SODIUM	ID
	076227		
6/29/2016	076256	LINAGLIPTIN/METFORMIN HCL	MC, TD, HD, LD
	076257		
	076152	DICLOFENAC SODIUM	DA, PG, MC, TD, ID, HD, LD

**PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:**

- Review list of GCNs with prospective DUR alerts turned on between April 1, 2016 and June 30, 2016 (**Table 1**).
- Any DUR Board recommendations for additions, deletions, and/or changes will be submitted to DHCS for review. Status of recommendations will be reported to the DUR Board at DUR Board meetings, as needed.



## **DUR EDUCATIONAL OUTREACH TO PROVIDERS ANTICHOLINERGIC LETTER**

**DATE OF MAILING: JUNE 17, 2016**

**DATE OF UPDATE: AUGUST 16, 2016**

### **OBJECTIVE**

- 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.

### **METHODS**

Any continuously eligible Medi-Cal fee-for-service beneficiary 65 years of age and older with regular, concomitant use of second-generation antipsychotic medications and anticholinergics was included in the study population. Regular use was defined as use of both a second-generation antipsychotic medication and an anticholinergic medication, each with a total days' supply greater than 180 days during the measurement year (between May 1, 2015, and April 30, 2016).

A total of 152 beneficiaries met the inclusion criteria listed above and on June 17, 2016, a total of 130 prescribers were sent a packet that included the following:

- A summary of clinical recommendations
- Medi-Cal DUR article on Anticholinergics
- Patient name and date of birth for all patients identified for this prescriber
- One provider response survey per patient

Of note, for this letter we received approval from DHCS to use National Provider Identifier (NPI) mailing addresses for all providers not listed in the Medi-Cal Master Provider File. A little less than half of the providers for this mailing were not listed in the Medi-Cal Master Provider File (n=53; 41%).

Timeframe of mailing following approval of packet by DHCS:

- Prescriber Letters (n=130)
  - Thursday, June 2, 2016: packet submitted to Publications
  - Wednesday, June 8, 2016: final, edited packet approved by DHCS/Xerox
  - Friday, June 10, 2016: packet sent to printer
  - Friday, June 17, 2016: packet mailed to providers

## OUTCOMES

- Direct costs associated with mailing:
  - A total of 130 letters were mailed for a total estimated cost of \$129.88
  - Each letter was estimated to have cost \$0.9991, which equals the cost of two envelopes and postage for two envelopes, as a self-addressed stamped envelope was included with each letter
- Rate of undeliverable letters (within 90 days):
  - Thus far, after 60 days, 16 prescribers (out of 130 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 12%.
  - The rate of returned mail among those providers with addresses in the Medi-Cal Master Provider File is higher (14%) when compared to providers with addresses obtained from their NPI (9%).
- Provider response rate (within 90 days):
  - Thus far, after 60 days, a total of 15 prescribers (out of 130 unique prescribers) returned 15 patient surveys, for a provider response rate of 12%. The response rate is similar among those providers with addresses obtained from the NPI file (11%) and those listed in the Medi-Cal Master Provider File (12%)
  - If undeliverable letters are removed from the denominator, the response rate increases to 13% (15 out of 114 unique prescribers)
  - The 15 patient surveys received thus far represent 10% of patient profiles in this mailing

As stated in the original proposal, the following outcome variable will be assessed at a later time point, as medical and pharmacy claims data become available:

- The primary outcome variable will be the percentage of the continuously-eligible study population with a total days' supply greater than 90 days for both an anticholinergic and an atypical antipsychotic in the 6-month period following the mailing of the intervention letter (July 1, 2016 through December 31, 2016).



## **DUR EDUCATIONAL OUTREACH TO PROVIDERS UPDATE: ASTHMA LETTER**

**DATE OF MAILING:** MAY 26, 2015 and MAY 29, 2015

**DATE OF UPDATE:** AUGUST 4, 2015 and SEPTEMBER 26, 2015 and AUGUST 16, 2016

### **OBJECTIVES**

- To improve the quality of asthma care in the Medi-Cal fee-for-service (FFS) population.
- To determine if including patient-specific profiles in an educational DUR outreach letter to providers results in improved outcomes over a generic mailing.

### **METHODS**

The dataset used in writing the Medi-Cal DUR educational bulletin on asthma was used to identify Medi-Cal FFS beneficiaries with 1) four or more dispensing events for asthma rescue medications without an outpatient visit in which asthma was one of the listed diagnoses during the measurement year; and 2) an asthma medication ratio (AMR) < 0.50 during the measurement year.

Further inclusion criteria for the educational DUR educational outreach to providers included the following:

- Continuous eligibility in Medi-Cal FFS between September 1, 2013 and April 30, 2015;
- At least four or more dispensing events for asthma rescue medications AND/OR at least one emergency department visit where the primary or secondary ICD-9 code was asthma, AND/OR at least one inpatient hospital visit where the primary or secondary ICD-9 code was asthma between September 1, 2013 and April 30, 2015 (the definitions of "persistent asthma," according to HEDIS);
- No known outpatient visits where the primary or secondary ICD-9 code was asthma between September 1, 2013 and April 30, 2015; and
- Continuous AMR calculation of < 0.50 between September 1, 2013 and April 30, 2015; and
- At least one prescriber with a National Provider Identifier (NPI) number linked to an available Medi-Cal provider mailing address.

Further exclusion criteria for the educational DUR educational outreach to providers included the following:

- Beneficiaries with AMR calculations  $\geq 0.50$  between May 1, 2014 and April 30, 2015
- Co-morbid medical conditions beyond those listed in the HEDIS criteria that may impair lung function and breathing ability (includes congenital quadriplegia, pulmonary embolism, muscular dystrophy, spina bifida) and/or beneficiaries with breathing and/or feeding tubes.

Each patient profile was reviewed by two pharmacists and any conditions resulting in medical exclusions were sent to a physician for final review.

A total of 33 beneficiaries with asthma medications prescribed by 77 different providers met all of the above inclusion/exclusion criteria. Two providers had more than one beneficiary in the cohort (one had two beneficiaries, and one had three beneficiaries), so in order to avoid these prescribers being randomized into separate groups, they were randomized as a batch.

The results of the randomization are as follows:

- Control group: 17 beneficiaries and 42 prescribers
- Intervention group: 16 beneficiaries and 35 prescribers

### **Control Group**

Prescribers randomized to this group were mailed a packet including the following:

- Letter describing the Medi-Cal DUR article on asthma quality-of-care
- Medi-Cal DUR article on asthma quality-of-care
- General survey

### **Intervention Group**

Prescribers randomized to this group were mailed a packet including the following:

- Letter describing the Medi-Cal DUR article on asthma quality-of-care that included the recommendation to schedule an outpatient visit for each patient profile included with the mailing, in order to evaluate asthma control
- Patient profile(s) with patient name, date of birth, history of paid pharmacy claims for asthma rescue and asthma controller medications (from September 1, 2011 through April 30, 2015), history of emergency department visits and inpatient hospitalizations where the primary diagnosis or secondary diagnosis was listed as asthma (from September 1, 2011 through April 30, 2015)
- Medi-Cal DUR article on asthma quality-of-care
- Surveys: one for each patient profile and one general survey

Due to multiple address listings for some providers, a total of 46 control letters and 37 intervention letters were drafted for mailing. To reduce provider burden, if there were multiple patient profiles for a single prescriber, all patient profiles and surveys were sent together.

Timeframe of each mailing following approval of packet by DHCS:

- Control Letters (n=46)
  - Thursday, May 7, 2015: packet submitted to Publications
  - Tuesday, May 19, 2015: final, edited packet approved by DHCS/Xerox
  - Wednesday, May 20, 2015: packet sent to printer
  - Tuesday, May 26, 2015: packet mailed to providers
- Intervention Letters (n=37)
  - Wednesday, May 13, 2015: packet submitted to Publications
  - Thursday, May 26, 2015: final, edited packet approved by DHCS/Xerox
  - Thursday, May 26, 2015: packet sent to printer
  - Friday, May 29, 2015: packet mailed to providers

## OUTCOMES

- Direct costs associated with mailing:
  - A total of 83 letters were mailed for a total cost of \$82.93.
  - Each letter was estimated to have cost \$0.9991, which equals the cost of two envelopes and postage for two envelopes, as a self-addressed stamped envelope was included with each letter
- Rate of undeliverable packets:
  - A total of 14 packets (out of 46) were returned to sender as undeliverable from the control group, for an undeliverable rate of 30%
  - A total of 7 packets (out of 37) were returned to sender as undeliverable from the intervention group, for an undeliverable rate of 19%
  - Overall undeliverable rate was 25%
- Provider response rate (within 90 days):
  - A total of 1 survey (out of 46) was returned within 90 days post-mailing from the control group, for a provider response rate of 2%
  - A total of 9 surveys (out of 37) were returned within 90 days post-mailing from the intervention group, for a provider response rate of 24%

As stated in the original proposal, the following outcome variables will need to be assessed at later time points, as claims data becomes available:

The following primary outcome variable was assessed at 90-days following the packet mailing date in a subgroup of continuously eligible Medi-Cal FFS beneficiaries, with the analysis scheduled to be presented at the next DUR Board meeting in November:

- Percentage of beneficiaries with an outpatient visit in which asthma was one of the listed diagnoses (by control and intervention groups, in aggregate).

Medical and pharmacy claims data with dates of service between May 1, 2015 and August 31, 2015 were reviewed for this update. Of note, there was one beneficiary from the control group that was no longer enrolled in the Medi-Cal fee-for-service program as of July 2015, which left 16 beneficiaries in the control group and 16 beneficiaries in the intervention group.

- Outpatient visits within 90 days of mailing: control group (2/16 = 12%)
- Outpatient visits within 90 days of mailing: intervention group (1/16 = 6%)

One of the two control beneficiaries with an outpatient office visit also had two visits to the emergency department during this timeframe. No other beneficiaries had paid claims for emergency department visits or inpatient hospitalizations within 90 days of the mailing.

The following secondary outcome variable was assessed at six months following the packet mailing date in the subgroup of continuously eligible Medi-Cal FFS beneficiaries:

- Total reimbursement paid to pharmacies for all asthma-related pharmacy claims:
  - By individual utilizing beneficiary:
    - Control (n=14): average increase of \$130.70 per beneficiary
    - Intervention (n=14): average increase of \$241.24 per beneficiary
  - By group (in aggregate):
    - Control (n=14): \$1968.77 during the 6 months prior to the mailing vs. \$3798.63 during the 6 months following the mailing

- Intervention (n=14): \$2776.94 during the 6 months prior to the mailing vs. \$6154.26 during the 6 months following the mailing

The following secondary outcome variables were assessed for the 12 months following the packet mailing date in a subgroup of 28 continuously eligible Medi-Cal FFS beneficiaries (n=14 in the control group and n=14 in the intervention group):

- Percentage of beneficiaries with an AMR  $\geq 0.50$  (among beneficiaries still taking any medication for asthma):
  - Control:  $1/8 = 13\%$
  - Intervention:  $4/7 = 57\%$
- The net change in AMR by individual utilizing beneficiary (among beneficiaries still taking any medication for asthma):
  - Control (n=8): +0.01
  - Intervention (n=7): +0.25
- Rate of emergency department visits where the primary diagnosis is asthma (by control and intervention groups, in aggregate):
  - Control (n=14):  $1/14 = 7\%$
  - Intervention (n=14):  $3/14 = 21\%$
- During this time period there were no inpatient hospitalizations in either group where the primary diagnosis was asthma.

## CONCLUSIONS

The timing of the letters from submission to Publications and mailing to providers was approximately two and one-half weeks, which continues to be a reasonable timeframe. The higher response rate among the intervention group, in comparison to the control group (24% vs. 2%), provides some preliminary supportive evidence that including patient profiles with DUR educational outreach letters may improve provider response to future surveys.

Importantly, responses collected through provider surveys remain unanimously positive, supporting continued direct mailing of letters to providers as an acceptable mechanism for future DUR educational outreach efforts.

Finally, two limitations encountered previously unfortunately persisted with this mailing: 1) the use of the existing database of Medi-Cal provider addresses led to an overall undeliverable rate of 25%, and 2) provider return mailing responses were incompletely scanned, resulting in significant data loss to the project (a total of six missing general or patient-specific surveys).

While the policy remains in place that we must use the addresses in the Medi-Cal provider master file, continuing efforts to improve the completeness and accuracy of the Medi-Cal provider master file will hopefully lead to improvements in future mailings. In addition, as of August 4, 2015 the Retrospective DUR Educational Outreach Mailings Standard Operating Procedure (SOP) now reflects that provider returned mailing responses will be shredded only after verification by the Xerox DUR pharmacist, in order to prevent potential data loss due to incorrect processing and scanning of all response or return mailings received.

## PROPOSED RECOMMENDATIONS TO THE DUR BOARD:

- Continue to recommend DUR educational outreach to providers through at least four direct mailings per year.
  - As appropriate, mailings should include protected health information.

- All proposals will be presented to the DUR Board for input prior to mailing and any DUR Board recommendations for additions, deletions, and/or changes will be submitted to DHCS for review.
- Status of recommendations will be reported to the DUR Board at DUR Board meetings, as needed.
- DUR Board recommendations for additions, deletions, and/or changes to this reporting format will be submitted to DHCS for review.



**DUR EDUCATIONAL OUTREACH TO PROVIDERS  
MORPHINE EQUIVALENT DAILY DOSE (MEDD) LETTER**

**DATE OF MAILING: MARCH 9, 2016 and MARCH 11, 2016 and JULY 21, 2016**

**DATE OF UPDATE: APRIL 12, 2016 and AUGUST 16, 2016**

**OBJECTIVE**

- To improve the quality of pain treatment among non-cancer, non-hospice Medi-Cal fee-for-service beneficiaries at increased risk of opioid overdose.

**METHODS**

A morphine equivalent daily dose (MEDD) was calculated for any Medi-Cal fee-for-service beneficiary with a paid pharmacy claim for a prescription opioid medication between July 1, 2015 and December 31, 2015. A total of 39,713 paid claims exceeded > 80 mg MEDD, representing 10,167 Medi-Cal fee-for-service beneficiaries.

The following inclusion/exclusion criteria were applied in a stepwise order to these 10,167 beneficiaries to determine the size of the study population:

- A total of 5,157 beneficiaries were excluded as they were currently receiving buprenorphine as part of a narcotic withdrawal treatment plan between July 1, 2015 and December 31, 2015
- A total of 1,848 beneficiaries had approved Treatment Authorization Requests (TARs) on file for opioid paid claims between July 1, 2015 and December 31, 2015
- A total of 1,084 beneficiaries were not continuously-eligible in the Medi-Cal fee-for-service program since July 1, 2015 (including January 2016)
- A total of 336 beneficiaries had a primary or secondary diagnosis of cancer between January 1, 2015 and December 31, 2015
- A total of 321 beneficiaries resided in a long-term care facility or received hospice care between January 1, 2015 and December 31, 2015

This left a study population of 1,421 beneficiaries with 3,340 paid claims that exceeded > 80 mg MEDD, for a total of 1,147 providers. As the total number of provider letters for this mailing would exceed 500 letters, the MEDD threshold was adjusted to > 120 mg MEDD.

With the threshold 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. We then reviewed the prescriber NPI to determine that of those 380 prescribers, a total of 218 had current

mailing addresses listed in the Medi-Cal Master Provider File (representing 259 beneficiaries and 951 paid claims).

A final review of the medical and pharmacy claims for the 259 beneficiaries was conducted 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).

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

Timeframe of mailing following approval of packet by DHCS:

- Prescriber Letters (n=134)
  - 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 providers
- Updated Prescriber Letters (n=21)
  - Thursday, July 21, 2016: patient profiles were updated and packets were mailed again to all qualified providers who had packets returned as undeliverable during first mailing; data were current through June 30, 2016 (previously went through February 29, 2016)

## OUTCOMES

- Direct costs associated with mailing:
  - A total of 134 letters were mailed for a total estimated cost of \$138.88
  - Each letter was estimated to have cost \$0.9991, which equals the cost of two envelopes and postage for two envelopes, as a self-addressed stamped envelope was included with each letter
  - A total of 23 letters were updated and resent to different addresses, for an estimated additional cost of \$22.98, for a revised total estimated cost of \$161.86.
- Rate of undeliverable letters (within 90 days):
  - A total of 32 prescribers (out of 132 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 24%
  - Of the 23 letters that were resent on July 21, 2016, as of August 16, 2016, only one of these 23 letters has been returned as undeliverable.
- Provider response rate (within 90 days):
  - A total of 30 prescribers (out of 132 unique prescribers) returned 34 patient surveys, for a provider response rate of 23%
  - The 34 patient surveys received thus far represent 22% of patient profiles in this mailing
  - Of the 23 letters that were resent on July 21, 2016, as of August 16, 2016, a total of 5 prescribers have returned 5 patient surveys (these responses are included in the above numbers).

### **Survey responses (n=34)**

- A total of 27 patient surveys (79%) indicated that the patient was currently under their care, with the following responses (respondents could check more than one option):
  - “Has an appointment to discuss drug therapy” (n=19; 70%)
  - “I have reviewed the information and will modify drug therapy” (n=9; 33%)
  - “I have tried to modify drug therapy, however the symptoms reoccurred” (n=6; 22%)
- A total of 5 patient surveys indicated that the provider would prescribe naloxone for the patient
- A total of 11 patient surveys contained written comments from providers.
  - The majority of comments discussed tapering/weaning plan in process or completed (n=6; 55%)
  - Other comments described either provider’s monitoring efforts or offered additional background about the patient history and/or regimen.
  - One provider stated they were previously unaware of a patient’s recent emergency department visit for opioid poisoning.

As stated in the original proposal, the following outcome variables will need to be assessed at later time points, as medical and pharmacy 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; August 1, 2016 through January 31, 2017 for those letters that were re-sent)

- 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; August 1, 2016 through January 31, 2017 for those letters that were re-sent):
  - 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 take-home naloxone
  - 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)



## Medi-Cal DUR Educational Outreach to Providers: Buprenorphine Intervention Proposal

### Background:

Each day in the United States, 46 people die from an overdose of prescription opioid pain relievers.<sup>1</sup> In 2012, there were approximately 2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers and an estimated 467,000 addicted to heroin.<sup>2</sup>

The Drug Addiction Treatment Act of 2000 (DATA 2000) established a new paradigm for the medication-assisted treatment (MAT) of opioid addiction in the United States and enabled physicians to provide office-based treatment for opioid addiction.<sup>3</sup> This act allowed physicians to prescribe Schedule III, IV, or V medications that are approved by the United States Food and Drug Administration (FDA) for patients with opioid-use disorders. In October 2002, the FDA approved two Schedule III medications for the treatment of opioid addiction, the opioid partial agonist medication buprenorphine and a combination of buprenorphine and naloxone (an opioid antagonist).<sup>3,4</sup>

Since that time, buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction.<sup>3-7</sup> Buprenorphine has a reduced risk of overdose relative to full agonist therapies, and in combination with naloxone, has reduced abuse liability.<sup>3-6</sup> Buprenorphine is about 20 – 30 times more potent than morphine as an analgesic; however, high doses of buprenorphine have been shown to have a blunting effect on both physiological and psychological effects due to it being an opioid partial agonist.<sup>8</sup> By adding naloxone to buprenorphine, the potential euphoric high resulting from the injection of buprenorphine can be blocked.<sup>8</sup> Several reviews have concluded there is high-quality evidence to show that MAT with buprenorphine is effective in the maintenance treatment of opioid addiction and increases retention in treatment.<sup>3,5,9</sup>

Despite the success of MAT with buprenorphine-containing products, this treatment is highly underutilized and access is often restricted. In 2013, the Centers for Medicare & Medicaid Services (CMS) reported that prior authorization for buprenorphine use was required by 48 Medicaid programs and several states had lifetime limits on buprenorphine, even though evidence shows that opioid addiction is a chronic condition that may require ongoing treatment.<sup>10</sup> Recent efforts at the national level have been aimed at expanding access and removing restrictions to buprenorphine, including modification of legislative rules to increase the number of patients that providers are able to treat under the DATA 2000 waiver.<sup>11</sup> Currently, as of August 8, 2016, qualified prescribers may now treat up to 275 patients (up from 30 patients in 2000).<sup>11</sup> The stated intent of this increase was to allow greater access to buprenorphine-based MAT.<sup>11</sup>

Policy changes within the Medi-Cal program have also aimed to improve access to buprenorphine-containing products. Starting June 1, 2015, an approved TAR is no longer required for either buprenorphine or buprenorphine/naloxone when prescribed by qualified physicians for the treatment of individuals with opioid addiction. In addition, new formulations continue to be added as covered

benefits for Medi-Cal beneficiaries, including the buccal film formulation of buprenorphine/naloxone, effective September 1, 2015.

### **Buprenorphine Use in the Medi-Cal Fee-for-Service (FFS) Population:**

A retrospective cohort study was conducted to assess use of buprenorphine in the Medi-Cal fee-for-service population during the year following the policy change to not require an approved TAR. The initial study population included all continuously-eligible Medi-Cal fee-for-service beneficiaries with at least one paid claim for buprenorphine or buprenorphine/naloxone between June 1, 2015, and May 31, 2016.

Adherence to buprenorphine therapy was calculated for each beneficiary by determining the medication possession ratio (MPR), which calculates the sum of the days' supply for all claims during a defined period of time divided by the number of days elapsed during the period. For this analysis, the MPR was calculated beginning with the date of the first paid claim for buprenorphine during the measurement year, using the following equation:

$$\text{MPR} = \frac{\text{total days' supply for all buprenorphine paid claims for days between June 1, 2015, and May 31, 2016 (the measurement year)}}{\text{total days between the first buprenorphine paid claim date during the measurement year and May 31, 2016 (the last day of the measurement year)}}$$

In order to account for beneficiaries with paid claims for days that extended beyond the measurement year, any medication possession days after May 31, 2016 were subtracted from the total days' supply.

Additional analyses were performed to evaluate the concomitant use of selected medications that may increase the risk of overdose and other adverse drug events among beneficiaries with paid claims for buprenorphine was also conducted. All paid claims for drugs that may increase the risk of respiratory depression and/or overdose were reviewed for the study population during the measurement year, including other opioid medications (besides buprenorphine), benzodiazepines, barbiturates, and prescription sleep aids. Concomitant use of these medications was also calculated for a subset of the study population with an MPR between 80% and 120% who appeared to be taking buprenorphine for opioid maintenance.

### **Results:**

A total of 5,657 continuously-eligible Medi-Cal fee-for-service beneficiaries had at least one paid claim for either buprenorphine or buprenorphine/naloxone between June 1, 2015, and May 31, 2016, with the majority of beneficiaries (n = 3,612; 64%) having 12 or fewer paid claims during the year. For this study population there were a total of 52,813 buprenorphine paid claims during the measurement year, with an average of 22.7 ± 9.7 (mean ± standard deviation) days' supply per claim (range: 1 – 90 days). Almost half of buprenorphine paid claims (n=24,491; 46%) were for a supply of less than 30 days). During the one-year measurement period, the average number of claims for buprenorphine-containing products per beneficiary was 9.3 ± 7.5 claims, with an average days' supply during the year of 211.9 ± 136.5 days.

A review of demographic characteristics for the entire study population shows that beneficiaries with a paid claim for buprenorphine or buprenorphine/naloxone were predominantly 39 years of age and younger and white/Caucasian, non-Hispanic. The gender breakdown was almost equal, with 53% of the population male and 47% female. Finally, the distribution of beneficiaries by California region of residence shows the fewest beneficiaries in the study population reside in the Los Angeles and

Central Valley regions, while the more rural North and Mountain region had the greatest number of beneficiaries in the study population. This variation in region of residence may be impacted by the migration of beneficiaries in specific counties into Medi-Cal managed care plans (MCPs).

As measured by the MPR, a total of 2,628 beneficiaries (47%) had a buprenorphine adherence rate between 80% and 120% during the measurement year. This means the amount of buprenorphine dispensed for these beneficiaries was for approximately the same number of days than had elapsed since the first paid claim for buprenorphine in the measurement year, within a reasonable error window on either side. Based on these data, these beneficiaries were included in the opioid maintenance population. Only a small portion (n = 130, 2%) of the study population had an MPR greater than 120%, which meant the amount of buprenorphine dispensed was for a greater number of days than had elapsed. The remaining 2,899 beneficiaries (51%) had an MPR less than 80%. Among the 2,628 beneficiaries classified into the opioid maintenance subgroup, the average number of claims for buprenorphine-containing products per beneficiary increased to 13.5 ± 6.5 claims, with an average days' supply during the year of 321.5 ± 67.7 days.

As shown in Table 4, there were very few beneficiaries in the study population with paid claims for selected drugs that may increase the risk of overdose and other adverse drug events when taken with buprenorphine-containing products, and even less use of these drugs among those in the opioid maintenance group. Among those 157 beneficiaries with at least one paid claim for any other opioid medication, more than half had only one paid claim (n = 90; 57%). When these opioid claims were reviewed for temporal proximity, the vast majority of these beneficiaries were tapering to opioids with a lower morphine equivalency before initiating buprenorphine therapy or the claims were prior to a paid claim for a buprenorphine-containing product. Among those in the opioid maintenance group, almost all beneficiaries (n = 34; 83%) had a total days' supply of other opioid medications of 30 days or less.

**Table 4. Use of Selected High-Risk Medications among Medi-Cal Fee-for-Service Beneficiaries with at Least One Paid Claim for Buprenorphine-Containing Products between June 1, 2015, and May 31, 2016**

	Entire Study Population (n=5,657)	Opioid Maintenance Group (n=2,628)
Concomitant use of:		
• Any other opioid medication	(n = 157), 3%	(n = 41), 2%
• Any benzodiazepine	(n = 101), 2%	(n = 35), 1%
• Any prescription sleep aid	(n = 30), < 1%	(n < 10), < 1%
• Any barbiturate	(n < 10), < 1%	(n < 10), < 1%

Finally, a review of the 656 beneficiaries with only one paid claim for buprenorphine indicated a slightly higher rate of paid claims for other opioids during this one-year period (n = 36; 5%), more than double the rate of the opioid maintenance group.

**Objectives:**

- To inform providers that buprenorphine use among Medi-Cal fee-for-service beneficiaries is associated with high adherence rates and decreased concomitant use of high-risk medications, including other opioids.
- To increase the number of Medi-Cal patients receiving treatment with buprenorphine.
- To increase the number of Medi-Cal providers able to provide buprenorphine treatment.

## Methods:

An evaluation will be done to identify the top 100 prescribers (by total quantity prescribed) of opioids in the Medi-Cal fee-for-service program. Providers will be ranked by overall total quantity, and then by total quantity of selected opioids between January 1, 2016 and June 30, 2016. These providers will be cross-referenced to the list of California providers with a current waiver to provide buprenorphine treatment.

Providers who are among the top prescribers of opioids and who do not currently have a buprenorphine waiver will be sent a letter (**Appendix A**) with more information about buprenorphine training. The mailing will also include the following:

- Provider's rankings (by total quantity prescribed) of opioid prescribing in the Medi-Cal fee-for-service population
- Medi-Cal DUR article on buprenorphine
- Provider response survey (**Appendix B**) for each provider

An additional evaluation will be done to identify the top 100 prescribers (by total number of patients) of buprenorphine in the Medi-Cal program. Providers will be ranked by total number of patients with a paid claim for buprenorphine between July 1, 2015 and June 30, 2016.

Providers who are among the top prescribers of buprenorphine will be sent a letter (**Appendix C**) thanking them for obtaining the waiver and letting them know that the maximum number of patients that qualified providers can treat has been raised to 275. The mailing will also include the following:

- Medi-Cal DUR article on buprenorphine
- Provider response survey (**Appendix B**) for each provider

## Outcomes:

The primary outcome variable will be the percentage increase in the number of patients (all of Medi-Cal) with paid claims for buprenorphine among all providers who received the mailing, calculated one year prior to and one year after the mailing of the letter.

The following secondary outcome variables will also be assessed after one year:

- The number of providers contacted who complete the training and applied for a waiver
- Percentage change (by total quantity prescribed) of total opioid prescribing in the Medi-Cal fee-for-service population, by individual provider among providers contacted that were in the Top 100.

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.

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## Appendix A. Letter to Providers without Waiver.

«Date»

«Provider\_Title» «Provider\_First\_and\_Middle\_Name» «Provider\_Last\_Name»  
«Prvdr\_Physical\_Street\_1\_Address» «Prvdr\_Physical\_Street\_2\_Address»  
«Prvdr\_Physical\_City», CA «Prvdr\_Physical\_Zip\_Code»

### RE: Retrospective Drug Utilization Review Buprenorphine Initiative

Dear Provider,

Buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction. Several reviews have concluded there is high-quality evidence to show that medication-assisted treatment (MAT) with buprenorphine is effective in the maintenance treatment of opioid addiction and increases retention in treatment.

Despite the success of MAT with buprenorphine-containing products, this treatment is highly underutilized and access is often restricted. Recent efforts at the national level have been aimed at expanding access and removing restrictions to buprenorphine, including modification of legislative rules to increase the number of patients that providers are able to treat under the DATA 2000 waiver. Currently, as of August 8, 2016, qualified prescribers may now treat up to 275 patients.

Policy changes within the Medi-Cal program have also aimed to improve access to buprenorphine-containing products. Starting June 1, 2015, an approved *Treatment Authorization Request* is no longer required for either buprenorphine or buprenorphine/naloxone when prescribed by qualified physicians for the treatment of individuals with opioid addiction. In addition, new formulations continue to be added as covered benefits for Medi-Cal beneficiaries, including the buccal film formulation of buprenorphine/naloxone, effective September 1, 2015.

A recent analysis by the Medi-Cal Drug Use Review (DUR) program found that 47% of Medi-Cal fee-for-service beneficiaries with a paid claim for buprenorphine in the past year continue to be adherent to their buprenorphine treatment regimen. Concomitant use of any opioid among beneficiaries with at least one paid claim for buprenorphine was also very low (3%), and even lower in the adherent group (2%). The full publication is included with this mailing for your review and can be found on the Medi-Cal DUR website at: [website].

For your reference, you are receiving this letter as you are one of the top 100 prescribers (by total quantity prescribed) of opioids in the Medi-Cal fee-for-service program. In addition, we do not see that you are currently certified to offer buprenorphine treatment and would encourage you to do so, as there is a shortage of providers who are qualified to provide this treatment in California.

More information about the eight-hour buprenorphine training and how to apply for a waiver to provide buprenorphine treatment to your patients is available in this mailing.

The success of the Medi-Cal DUR program is enhanced by the two-way exchange of information. Therefore, we would appreciate learning of your assessment of this information. Although your participation is voluntary, we would find your feedback helpful as we expand our educational outreach efforts.

At your convenience, please complete the enclosed survey(s) and return survey(s) using the enclosed self-addressed stamped envelope. If you have any questions or concerns about this information or our request, please contact Ivana Thompson, DUR Pharmacist, at (916) 295-9488.

Thank you for your professional consideration of this information and request for response, as well as your continued participation in the Medi-Cal program.

Sincerely,

*Mike Wofford*

Michael Wofford, Pharm D.  
Chief, Pharmacy Policy Branch

**Appendix B. Provider Survey.**



**PROVIDER RESPONSE SURVEY**

What did you think of the enclosed information provided on buprenorphine? (check one)

- I did not review the enclosed information
- I reviewed the enclosed information and found it very useful
- I reviewed the enclosed information and found it somewhat useful
- I reviewed the enclosed information and found it not useful

Would you like more information about buprenorphine training in your area?

- No
- Yes, I will contact the Xerox DUR Pharmacist at 916-295-9488
- Yes, please contact me at the following telephone number:

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What information would you find helpful in future mailings? (check all that apply)

- Patient-specific profiles using medical and pharmacy claims data
- Provider-specific profiles using medical and pharmacy claims data
- Other (please specify):

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Additional comments or suggestions:

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Thank you for participating in the California Medicaid Drug Utilization Review Program.

**Please return within 30 days of receipt using the enclosed self-addressed stamped envelope.**

## Appendix C. Letter to Providers with Waiver.

«Date»

«Provider\_Title» «Provider\_First\_and\_Middle\_Name» «Provider\_Last\_Name»  
«Prvdr\_Physical\_Street\_1\_Address» «Prvdr\_Physical\_Street\_2\_Address»  
«Prvdr\_Physical\_City», CA «Prvdr\_Physical\_Zip\_Code»

### RE: Retrospective Drug Utilization Review Buprenorphine Initiative

Dear Provider,

As you know, buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction. Several reviews have concluded there is high-quality evidence to show that medication-assisted treatment with buprenorphine is effective in the maintenance treatment of opioid addiction and increases retention in treatment.

A recent analysis by the Medi-Cal Drug Use Review (DUR) program found that 47% of Medi-Cal fee-for-service beneficiaries with a paid claim for buprenorphine in the past year continue to be adherent to their buprenorphine treatment regimen. Concomitant use of any opioid among beneficiaries with at least one paid claim for buprenorphine was also very low (3%), and even lower in the adherent group (2%). The full publication is included with this mailing for your review and can be found on the Medi-Cal DUR website at: *[website]*.

For your reference, you are receiving this letter as you are one of the top 100 prescribers (by total number of patients) of buprenorphine in the Medi-Cal fee-for-service program. We wanted to thank you for your dedication to treating opioid addiction in California and encourage you to continue to prescribe buprenorphine for qualified patients.

We also wanted to make sure you were aware of recent efforts at the national level to expand access and remove restrictions to buprenorphine, including modification of legislative rules to increase the number of patients that providers are able to treat under the DATA 2000 waiver. Currently, as of August 8, 2016, qualified prescribers may now treat up to 275 patients

The success of the Medi-Cal DUR program is enhanced by the two-way exchange of information. Therefore, we would appreciate learning of your assessment of this information. Although your participation is voluntary, we would find your feedback helpful as we expand our educational outreach efforts.

At your convenience, please complete the enclosed survey(s) and return survey(s) using the enclosed self-addressed stamped envelope. If you have any questions or concerns about this information or our request, please contact Ivana Thompson, DUR Pharmacist, at (916) 295-9488.

Thank you for your professional consideration of this information and request for response, as well as your continued participation in the Medi-Cal program.

Sincerely,

*Mike Wofford*

Michael Wofford, Pharm D.  
Chief, Pharmacy Policy Branch



## POLICY IMPACT REPORT

**DATES OF REVIEW:** August 16, 2016

### **FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:**

- ANTI-PSYCHOTICS, PHENOTHIAZINES
- ANTIPSYCHOTICS, DOPAMINE ANTAGONISTS, BUTYROPHENONES
- ANTIPSYCHOTICS, DOPAMINE ANTAGONISTS, DIPHENYLBUTYL-PIPERIDINES
- ANTIPSYCHOTICS, DOPAMINE ANTAGONISTS, THIOXANTHENES
- ANTIPSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG
- ANTIPSYCHOTICS, DOPAMINE & SEROTONIN ANTAGONISTS
- ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED

**DRUG PROBLEM TYPES:** Over Utilization (OU), Therapeutic Appropriateness (O<sup>1</sup>), Therapeutic/Ingredient Duplication (TD), Drug/Age Contraindication (O<sup>2</sup>)

**BACKGROUND:** In March 2015, the Drug Use Review (DUR) Program published an educational bulletin entitled, *“Improving the Quality of Care: Antipsychotic Use in Children and Adolescents.”* This bulletin evaluated the following two new measures that had been added to the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) for 2015:

- Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM), which assesses the percentage of children and adolescents who have ongoing use of antipsychotic medications and metabolic testing during the measurement year
- Use of Multiple Concurrent Antipsychotics in Children and Adolescents (APC), which assesses the percentage of children and adolescents who were taking two or more concurrent antipsychotics for at least 90 days during the measurement year.

This bulletin used October 1, 2013, through September 30, 2014 as the measurement year. Of the 6,013 children and adolescents identified with at least two paid claims for an antipsychotic medication during the measurement year, only 37.4% had paid claims for metabolic monitoring during that same time period (both blood glucose or HbA1C and LDL-C or cholesterol).

Finally, of the 5,375 children and adolescents with at least 90 consecutive days of antipsychotic medication treatment during the measurement year, a total of 306 (5.7%) were taking two or more concurrent antipsychotics for at least 90 days during the measurement year.

**DESCRIPTION OF POLICY CHANGE:** Effective October 1, 2014, any use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age requires an approved *Treatment Authorization Request (TAR)*.

**OBJECTIVE:** The objective of this report is to evaluate pharmacy and medical claims data for the year after the TAR requirement was implemented, in order to determine the impact of the policy change on the Medi-Cal fee-for-service population.

**METHODS:** To account for the transition period while the policy was being implemented, the measurement year for the analyses was calendar year 2015, in order to allow three months for the implementation of the new policy, which took effect on October 1, 2014. Results from 2015 will be compared to baseline data from the year preceding the policy change (paid claims between October 1, 2013, and September 30, 2014).

Paid pharmacy and medical claims for Medi-Cal fee-for-service beneficiaries with dates of service between January 1, 2015 and December 31, 2015, were reviewed for all Medi-Cal fee-for-service beneficiaries 1 – 17 years of age who had at least one paid claim for an antipsychotic medication during this time period. To be included in the study population, continuous eligibility in the Medi-Cal fee-for-service program was required between January 1, 2015, and December 31, 2015, to allow for complete medical and pharmacy claims data.

**RESULTS:** There were a total of 4,281 continuously eligible Medi-Cal fee-for-service beneficiaries between 1 age 17 years of age with at least one paid claim for an antipsychotic medication between January 1, 2015, and December 31, 2015.

The demographic makeup of this study population is almost exactly the same as in the original analysis. The study population remains almost 2/3 male (64%, compared with 65% in the previous study population) and almost half of the beneficiaries identify as white/Caucasian race, non-Hispanic ethnicity (48%, compared with 47% in the previous study population).

For the APM calculation (Table 1), beneficiaries were excluded if they had only one paid claim for an antipsychotic medication during the measurement year (leaving a denominator of 3,717 beneficiaries). Baseline rates are included for reference, and a percentage change has been calculated to show the difference between the two. Although the 38.9 percent figure calculated using HEDIS measure parameters gives the rate at which both tests were completed (blood glucose or HbA1C and LDL-C or cholesterol), individual testing rates were also calculated for the study population and were again found to be very similar to results before the policy change.

The rate of glucose or Hb1AC monitoring (52.0%, down from 52.4% from the previous study population), continues to be much greater than LDL-C or cholesterol monitoring (39.4%, up from 37.9% from the previous study population). While there was a slight improvement of beneficiary lipid testing, there still is an opportunity for outreach to providers, who could raise the metabolic monitoring rate calculated in the HEDIS measure by ordering both tests at the same time.

**Table 1. Metabolic Monitoring in Children and Adolescents with ≥2 Paid Claims for Antipsychotic Medications During the Measurement Year (January 1, 2015, through December 31, 2015)\***

Age Group	Numerator Children and adolescents with ≥1 test for <b>both</b> blood glucose/HbA1C and LDL-C/cholesterol			Denominator Children and adolescents with ≥2 paid claims for antipsychotic medications			Percentage of children and adolescents with ≥2 paid claims for antipsychotic medications and metabolic testing		
	Baseline	2015	Change	Baseline	2015	Change	Baseline	2015	Change
1 – 5 years	18			68	29	<b>-57.4%</b>	26.5%		
6 – 11 years	575			1,838	1,056	<b>-42.5%</b>	31.3%		
12 – 17 years	1,653			4,107	2,632	<b>-35.9%</b>	40.2%		
<b>TOTAL</b>	<b>2,246</b>	<b>1,445</b>	<b>-35.7%</b>	<b>6,013</b>	<b>3,717</b>	<b>-38.2%</b>	<b>37.4%</b>	<b>38.9%</b>	<b>+1.5%</b>

\*Due to small cell size, some of these data cannot be stratified in the table (shaded black areas)

For the APC calculation (Table 2), beneficiaries were excluded from this calculation if they had less than 90 days of continuous antipsychotic medication treatment during the measurement year (leaving a denominator of 3,445 beneficiaries).

**Table 2. Children and Adolescents on Multiple Concurrent Antipsychotic Medications During the Measurement Year (January 1, 2015, through December 31, 2015)\***

Age Group	Numerator Children and adolescents on ≥2 concurrent antipsychotic medications ≥90 consecutive days			Denominator Children and adolescents with ≥90 consecutive days of antipsychotic medication treatment			Percentage of children and adolescents on ≥2 concurrent antipsychotic medications		
	Baseline	2015	Change	Baseline	2015	Change	Baseline	2015	Change
1 – 5 years	0			53	26	<b>-50.9%</b>	0.0%		
6 – 11 years	61			1,665	1,006	<b>-39.6%</b>	3.7%		
12 – 17 years	245			3,657	2,413	<b>-34.0%</b>	6.7%		
<b>TOTAL</b>	<b>306</b>	<b>227</b>	<b>-25.8%</b>	<b>5,375</b>	<b>3,445</b>	<b>-35.9%</b>	<b>5.7%</b>	<b>6.6%</b>	<b>+0.9%</b>

\*Due to small cell size, some of these data cannot be stratified in the table (shaded black areas)

This calculated rate of 6.6 percent of Medi-Cal fee-for-service beneficiaries on multiple concurrent antipsychotic medications is slightly higher (less than 1%) than before the policy change, although this may be a result of the greater overall reduction in the denominator (36% decrease), as compared with the reduction in the numerator (26%).

**PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:** Review and discuss the policy impact report. Proposed topics for discussion include the following:

- Advise and/or make recommendations for any further evaluation of antipsychotic use in children and adolescents.
- Discuss merits of ongoing educational outreach to providers regarding metabolic monitoring.
- Discuss whether additional educational outreach to providers should be developed targeting polypharmacy in children and adolescents.



## RETROSPECTIVE DUR REVIEW

**DATE OF REVIEW:** August 16, 2016

### **FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:**

- ANTIVIRALS, HIV-SPEC, NON-PEPTIDIC PROTEASE INHIB
- ANTIVIRALS, HIV-SPEC, NUCLEOSIDE-NUCLEOTIDE ANALOG
- ANTIVIRALS, HIV-SPEC., NUCLEOSIDE ANALOG, RTI COMB
- ANTIVIRALS, HIV-SPECIFIC, CCR5 CO-RECEPTOR ANTAG.
- ANTIVIRALS, HIV-SPECIFIC, FUSION INHIBITORS
- ANTIVIRALS, HIV-SPECIFIC, NON-NUCLEOSIDE, RTI
- ANTIVIRALS, HIV-SPECIFIC, NUCLEOSIDE ANALOG, RTI
- ANTIVIRALS, HIV-SPECIFIC, NUCLEOTIDE ANALOG, RTI
- ANTIVIRALS, HIV-SPECIFIC, PROTEASE INHIBITOR COMB
- ANTIVIRALS, HIV-SPECIFIC, PROTEASE INHIBITORS
- ANTIVIRALS, HIV-1 INTEGRASE STRAND TRANSFER INHIBTR
- ARTV CMB NUCLEOSIDE,NUCLEOTIDE,&NON-NUCLEOSIDE RTI
- ARV CMB-NRTI,N(T)RTI, INTEGRASE INHIBITOR

**DRUG PROBLEM TYPES:** Over Utilization (OU), Under Utilization (UU), Therapeutic Appropriateness (O<sup>1</sup>)

### **BACKGROUND:**

The Joint United Nations Programme on HIV/AIDS (UNAIDS) reports that approximately 36.7 million people globally are living with HIV.<sup>1</sup> Of those living with HIV, only 17 million people are receiving antiretroviral therapy (ART).<sup>1</sup> The use of ART has shown clear clinical benefits, reducing morbidity and mortality of HIV infection. Any treatment delays or interruptions have been related to rebound viremia, declining immune function and increased mortality rates. For this reason, ART should be utilized to achieve the treatment goals of maximally suppressing HIV RNA, preserving immune function, reducing HIV-associated morbidity, improving quality of life, and preventing HIV transmission.<sup>2</sup>

There are several categories of antiretroviral medications. These include nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), integrase strand transfer inhibitors (INSTI), protease inhibitors (PI), CCR5 co-receptor antagonists and fusion inhibitors. The initial ARV regimen for a treatment-naive patient generally consists of two NRTIs, usually abacavir/lamivudine (ABC/3TC), tenofovir alafenamide/emtricitabine (TAF/FTC), or tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in combination with a drug from one of three drug classes: an INSTI, an NNRTI, or a PI with a pharmacokinetic (BK) enhancer.<sup>2</sup>

Choosing an NRTI combination depends on differences in adverse events and efficacy. Main advantages of TAF and TDF over ABC include activity against hepatitis B and HLA-B\*5701 testing is

not required. The main advantages of ABC over TDF are renal adjustment is not required and it has less nephrotoxicity and deleterious effects on bone marrow density.<sup>2</sup>

When choosing the third drug in the combination therapy, clinical guidelines recommend consideration of the regimen's adverse effects profile, complexity, genetic resistance, and efficacy.<sup>2</sup> INSTI-containing regimens often are highly effective, have fewer adverse effects and have no significant CYP3A4 drug interactions. Head to head studies between INSTI and PI regimens proved INSTI was better tolerated with fewer treatment discontinuations. Currently all three available INSTIs are included in the recommended regimen and generally should be seen as first-line for most patients. Exceptions include patients unable to undergo resistance testing and those unlikely to adhere. For these patients, darunavir/ritonavir (DRV/r) may be an ideal choice as it has low rates of transmitted PI resistance, a high genetic barrier to resistance, and a low rate of treatment-induced resistance. Dolutegravir (DTG) is also a good alternative drug as its high barrier to resistance makes it unlikely that therapy will fail because of DTG resistance.<sup>2</sup>

In addition to patients with active HIV, prescribed daily oral antiretroviral pre-exposure prophylaxis (PrEP) significantly reduces the rate of HIV infection, especially among populations at high risk for HIV infection. Several clinical trials have demonstrated statistical significance in reduction of HIV transmission.<sup>2</sup> Effective for dates of service on or after April 1, 2014, the Medi-Cal program modified the indications for TDF/FTC to include prophylaxis therapy in HIV negative patients at risk of acquiring HIV infection, as well as for combination therapy in the treatment of HIV.

Adherence is critical for all patients on ART regimens. A pilot program conducted by Medi-Cal and the California Department of Health Care Services (DHCS) examined ART adherence and outcomes in a patient population receiving pharmacist-provided medication therapy management (MTM) services over a 3-year period. Results showed each year the pilot pharmacy patients had higher rates of remaining on a single type of ART regimen (71.7% vs 49.1%), were less likely to have excess fills (12.9% vs 35.5%), and were less likely to use contraindicated regimens (8.9% vs 12.2%).<sup>3</sup>

**ISSUES:** On January 1, 2014, California expanded Medi-Cal eligibility to include low-income adults with incomes at or below 138 percent of the federal poverty line. Between Q4 2013 and Q1 2014, the total population of eligible Medi-Cal beneficiaries increased by 12.9% and during this same time period there was a 69.6% increase in utilizing beneficiaries with at least one paid claim for an ART. As HIV antiretroviral medications are covered through the Medi-Cal fee-for-service program, the DUR program was asked to review use of these drugs across the entire Medi-Cal population.

**REVIEW OF CURRENT MEDI-CAL CRITERIA:** Pharmacy and claims data were reviewed for all Medi-Cal beneficiaries with at least one paid claim for any HIV antiretroviral medication between January 1, 2013, and December 31, 2015. Demographic, clinical, and enrollment data were obtained from a subset of these Medi-Cal beneficiaries that were continuously eligible in the Medi-Cal program for the duration of the 2014 calendar year.

As shown in Table 1, the number of utilizing beneficiaries with a paid claim for an HIV antiretroviral medication increased by 155% in the two years following the Medicaid expansion in California. For reference, Table 1 includes the year a drug was first approved by the FDA, in order to help explain some of the rapid increase in use of some of the newer medications.

**Table 1. Utilization of HIV Antiretroviral Medications among Medi-Cal Beneficiaries**

Drug Category	Drug	FDA Approval Year	On Medi-Cal List of Contract Drugs?	Total Utilizing Beneficiaries			% Change (2013 to 2015)
				2013	2014	2015	
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	zidovudine (ZDV) or azidothymidine (AZT)	1987	Y*	141	170	147	4.3%
	didanosine (ddl)	1991	Y*	26	30	18	-30.8%
	stavudine (d4T)	1994	Y*	73	71	48	-34.2%
	lamivudine (3TC)	1995	Y*	615	776	783	27.3%
	3TC + ZDV	1997	Y*	498	566	480	-3.6%
	abacavir (ABC)	1998	Y*	381	524	522	37.0%
	ABC +3TC + ZDV	2000	Y*	164	164	134	-18.3%
	emtricitabine (FTC)	2001	Y*	135	203	215	59.3%
	tenofovir (TDF)	2001	Y*	1,951	3,098	4,062	108.2%
	ABC + 3TC	2004	Y*	1,663	3,095	2,631	58.2%
TDF + FTC	2004	Y*	5,878	11,413	13,600	131.4%	
Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)	nevirapine (NVP)	1996	Y*	492	811	769	56.3%
	delavirdine (DLV)	1997	Y*	< 10	< 10	< 10	-100.0%
	efavirenz (EFV)	1998	Y*	414	593	486	17.4%
	etravirine (ETR)	2008	Y*	724	1,030	1,020	40.9%
	rilpivirine (RPV)	2011	Y*	86	170	269	212.8%
Integrase Strand Transfer Inhibitors (INSTIs)	raltegravir (RAL)	2007	Y*	2,357	3,671	3,736	58.5%
	dolutegravir (DTG)	2013	Y*	242	2,456	3,643	1405.4%
	elvitegravir (EVG)	2014	Y*	N/A	< 10	< 10	N/A
Protease Inhibitors	saquinavir (SQV)	1995	Y*	41	47	38	-7.3%
	indinavir (IDV)	1996	Y*	< 10	12	12	140.0%
	ritonavir (RTV)	1996	Y*	5,565	9,517	8,887	59.7%
	nelfinavir (NFV)	1997	Y*	100	101	69	-31.0%
	lopinavir (LPV) + RTV	2000	Y*	903	1,035	835	-7.5%
	atazanavir (ATV)	2003	Y*	2,984	4,331	3,747	25.6%
	fosamprenavir (FOS-APV)	2003	Y*	241	299	227	-5.8%
	tipranavir (TPV)	2005	Y*	11	12	10	-9.1%
darunavir (DRV)	2006	Y*	3,124	5,936	5,881	88.3%	
Fusion Inhibitors	enfuvirtide (T-20)	2003	N	16	15	14	-12.5%
CCR5 Co-Receptor Antagonists	maraviroc (MVC)	2007	Y*	156	266	260	66.7%
Multi-class Combination	EFV + FTC + TDF	2006	Y*	2,719	5,489	5,328	96.0%
	FTC + RPV + TDF	2011	Y*	951	2,645	3,206	237.1%
	EVG + cobicistat (c) + FTC + TDF	2012	Y*	722	3,661	5,338	639.3%
	ABC + DTG + 3TC	2014	Y*	N/A	518	3,713	N/A
	ATV + c	2015	Y*	N/A	N/A	325	N/A
	c + DRV	2015	Y*	N/A	N/A	1,260	N/A
	EVG + c + FTC + tenofovir alafenamide (TAF)	2015	Y*	N/A	N/A	30	N/A
	FTC + RPV +TAF	2016	Y*	N/A	N/A	N/A	N/A
FTC + TAF	2016	Y*	N/A	N/A	N/A	N/A	
<b>Total utilizing beneficiaries (any drug listed above)</b>				<b>13,877</b>	<b>28,681</b>	<b>35,335</b>	<b>154.6%</b>

\* Restrictions apply; for current information, use the online Medi-Cal Formulary search tool available on the [Formulary File](#) Web page of the Department of Healthcare Services (DHCS) website.

A total of 13,475 Medi-Cal beneficiaries with at least one paid claim for an HIV antiretroviral medication were identified as being continuously-eligible for Medi-Cal throughout 2014. Demographic characteristics for this population are summarized in Table 2, stratified by whether the beneficiary was enrolled in the Medi-Cal Fee-for-Service Program or a Medi-Cal managed care plan (as of December 2014).

**Table 2. Demographic Characteristics of Continuously-eligible Medi-Cal Beneficiaries with Paid Claims for HIV Antiretroviral Medication between January 1, 2014, and December 31, 2014.**

	<b>Medi-Cal Fee-for-Service Beneficiaries (n = 1,410)</b>	<b>Medi-Cal Managed Care Beneficiaries (n = 12,065)</b>	<b>p-value</b>
<b>Gender</b>			<b>0.38</b>
<ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> </ul>	<b>(n = 901), 64%</b> <b>(n = 509), 36%</b>	<b>(n = 7,851), 65%</b> <b>(n = 4,214), 35%</b>	
<b>Age</b>			<b>&lt; 0.001</b>
<ul style="list-style-type: none"> <li>• 39 years of age and younger</li> <li>• 40 years of age and older</li> </ul>	<b>(n = 445), 32%</b> <b>(n = 965), 68%</b>	<b>(n = 3,147), 26%</b> <b>(n = 8,918), 74%</b>	
<b>Race/Ethnicity</b>			<b>0.85</b>
<ul style="list-style-type: none"> <li>• White/Caucasian, non-Hispanic</li> <li>• All other races/ethnicities</li> </ul>	<b>(n = 341), 24%</b> <b>(n = 1,069), 76%</b>	<b>(n = 2,946), 24%</b> <b>(n = 9,119), 76%</b>	
<b>California Region of Residence (based on county)</b>			<b>&lt; 0.001</b>
<ul style="list-style-type: none"> <li>• Bay Area, including Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, Santa Clara, Santa Cruz, Solano, and Sonoma Counties</li> <li>• Southern California without Los Angeles, including Orange, Riverside, San Bernardino, San Diego, Santa Barbara, and Ventura Counties</li> <li>• Los Angeles County</li> <li>• Central/Southern Farm, including Fresno, Imperial, Kern, Kings, Madera, Merced, Monterey, San Benito, San Joaquin, San Luis Obispo, Stanislaus, and Tulare Counties</li> <li>• North and Mountain, including Alpine, Amador, Butte, Calaveras, Del Norte, Glenn, Humboldt, Inyo, Lake, Lassen, Mariposa, Mendocino, Modoc, Mono, Nevada, Plumas, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Tuolumne Counties</li> <li>• Central Valley, including Colusa, El Dorado, Placer, Sacramento, Sutter, Yolo, and Yuba Counties</li> <li>• Multiple Counties of Residence</li> </ul>	<b>(n = 292), 21%</b>  <b>(n = 290), 21%</b>  <b>(n = 595), 42%</b> <b>(n = 100), 7%</b>  <b>(n &lt; 10), &lt; 1%</b>  <b>(n = 44), 3%</b>  <b>(n = 84), 6%</b>	<b>(n = 3,405), 28%</b>  <b>(n = 1,910), 16%</b>  <b>(n = 4,364), 36%</b> <b>(n = 1,052), 9%</b>  <b>(n = 254), 2%</b>  <b>(n = 732), 6%</b>  <b>(n = 348), 3%</b>	

As shown in Table 2, only 10% of continuously-eligible beneficiaries with a paid claim for an HIV antiretroviral medication were enrolled in the Medi-Cal fee-for-service program, where they were more likely to be younger and live in Los Angeles County.

## PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Review and discuss the utilization data for the HIV antiretroviral medications and determine if there is a need for further evaluation.
- Discuss potential areas within this class of medications that might merit a DUR educational alert or bulletin. Given recent policy changes, new developments and therapies, consider a high-level review of antiretroviral therapy that could include an update of clinical guidelines and first-line therapies. Different subgroups for consideration could include the following:
  - Treatment-naïve patients, children and adolescents, women, hepatitis B and/or hepatitis B coinfection, illicit drug users, etc.
- Discuss possible additional drug therapeutic categories that may warrant similar analyses across the entire Medi-Cal program, which would include data from beneficiaries enrolled in fee-for-service and managed care.

## REFERENCES:

1. Joint United Nations Programme on HIV/AIDS. Fact sheet 2016: Global Statistics-2015. Available at: <http://www.unaids.org/en/resources/fact-sheet>. Accessed: August 18, 2016.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at: <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Accessed: August 18, 2016.
3. Hirsch JD, Gonzales M, Rosenquist A, et al. Antiretroviral therapy adherence, medication use, and health care costs during 3 years of a community pharmacy medication therapy management program for Medi-Cal beneficiaries with HIV/AIDS. *J Manag Care Pharm*. 2011 Apr;17(3):213-23. Available at: <http://dx.doi.org/10.18553/jmcp.2011.17.3.213>. Accessed: August 18, 2016.



University of California  
San Francisco

# Update: DUR Publications

Shal Lynch, PharmD, CGP  
Health Sciences Associate Clinical Professor  
Department of Clinical Pharmacy  
School of Pharmacy

September 20, 2016

# August 2016: DUR Educational Bulletin

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

### ■ Learning Objectives

- Review the induction, stabilization, and maintenance phases of the management of opioid addiction.
- Describe strategies for pharmacists and prescribers to promote successful opioid agonist treatment.
- Summarize best practices for responsible prescribing and dispensing of buprenorphine-containing products.

# August 2016: DUR Educational Bulletin - 1

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

### ■ Background

- Opioid abuse and overdose continues to be a significant public health issue in the United States
- DATA 2000 enabled physicians to provide office-based treatment for opioid addiction
- Buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction
- As of June 1, 2015, Medi-Cal no longer requires an approved *TAR* for buprenorphine when prescribed by qualified physicians for treatment of individuals with opioid addiction

# August 2016: DUR Educational Bulletin - 2

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

- Three phases of buprenorphine treatment:
  - Induction
    - Three to seven days
  - Stabilization
    - One to two months
  - Maintenance
    - Minimum of one year, may be lifelong

# August 2016: DUR Educational Bulletin - 3

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

- Retrospective cohort study to assess use of buprenorphine, adherence to buprenorphine treatment, and concomitant use of selected medications
- All continuously-eligible FFS beneficiaries
  - With at least one paid claim for buprenorphine between June 1, 2015 and May 31, 2016
  - Adherence measured by medication possession ratio (MPR)

# August 2016: DUR Educational Bulletin - 4

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

- A total of 5,657 beneficiaries in study population
  - Almost half of buprenorphine paid claims (46%) were for a days' supply less than 30 days
  - Predominantly 39 years of age and younger and white/Caucasian, non-Hispanic
  - Gender breakdown was almost equal (53% male)
- As measured by the MPR, a total of 2,628 beneficiaries (47%) had a buprenorphine adherence rate between 80% and 120%

# August 2016: DUR Educational Bulletin - 5

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

- Use of selected concomitant medications

	Entire Study Population (n=5,657)	Opioid Maintenance Group (n=2,628)
Any other opioid medication	(n = 157), 3%	(n = 41), 2%
Any benzodiazepine	(n = 101), 2%	(n = 35), 1%
Any prescription sleep aid	(n = 30), <1%	(n < 10), <1%
Any barbiturate	(n < 10), <1%	(n < 10), <1%

- The 656 beneficiaries with only one paid claim for buprenorphine had a slightly higher rate (5%) of paid claims for other opioids

# August 2016: DUR Educational Bulletin - 6

## Clinical Review: The Treatment of Opioid Addiction with Buprenorphine

- Clinical Recommendations for Providers
  - Providers are encouraged to complete 8 hours of training and apply for a waiver to prescribe buprenorphine
  - Providers with a waiver should aim to treat their allowed maximum number of patients (can be up as many as 275 patients as of August 8, 2016)
- Clinical Recommendations for Pharmacies
  - Ensure that buprenorphine is in stock and available to meet demand for frequent refills
  - Create a safe and welcoming environment

# Future Topics: Bulletins

## DUR Educational Bulletins:

- Summarize use of antibiotics, with a special emphasis on new FDA safety warnings and the appropriate use of fluoroquinolone antibiotics
- Summarize relative risk of QT interval prolongation due to adverse drug reactions (in-progress)
- Promotion of appropriate prescribing of skeletal muscle relaxants, including an evaluation of concomitant use of opioids and benzodiazepines
- Provide treatment guidelines for managing pain in population with co-morbid mental health conditions, including those with a documented history of substance abuse
- Nicotine replacement therapy – to be timed with implementation of pharmacist furnishing of NRT
- Topics from today's meeting: HIV antiretrovirals, policy impact

# Future Topics: Alerts/Prospective Reviews

## DUR Educational Alerts:

- Annual vaccine alert, including any updates on current guidelines (ongoing, published each September)
- FDA drug safety communications for drugs on the Medi-Cal List of Contract Drugs (ongoing)

## Prospective DUR Reviews:

- Therapeutic duplication alert (Section 20, on agenda for November 2016)
- Top 20 alert/drug combinations by volume (on agenda for November 2016)
- Annual review of categories for duplicate therapy (Section 25, ongoing)
- Discrepancy clean-up (Section 20, ongoing)
- Quarterly review of new GCNs (ongoing)

# Future Topics: Retrospective Reviews

## Retrospective DUR Reviews:

- HCV polymerase inhibitors (in-progress, on agenda for November 2016)
- Assessment of opioid use and mortality, linking death index information with medical/pharmacy claims data
  - Concomitant use of benzodiazepines
  - Gender disparities
- Annual review of drugs added to the Medi-Cal List of Contract Drugs (ongoing, presented each November)
- New 2016 Adult Core Set Measures:
  - Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)
  - Use of Opioids at High Dosage (OHD)

**UCSF**

University of California  
San Francisco



# Medi-Cal Drug Utilization Review Board Meeting Pharmacy Updates

Pauline Chan, R.Ph., MBA

Pharmacy Policy Branch

09-20-16

## Topics

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- CMS Update:
  - Antipsychotic Drug Use in Children (ADC) Affinity Group
  - Prescription Opioids Abuse Actions
  - 2018 CMS DUR Annual Report Planning Committee
- DHCS Quality Strategy annual update
- Child Core Set Measures
- Adult Core Set Measures
- Academic Detailing Conference Working Agenda



## Antipsychotic Drug Use in Children Affinity Group (ADC)

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- **Goals:**
  - CMS plans to support state efforts to improve quality of care
- **Benefits to States:**
  - Learning opportunities
  - Regular meetings/communication with CMS
- **Participants:**
  - State Medicaid agency staff (with responsibility for fee-for-service or managed care)
- **Timeline/Commitment:**
  - Monthly 1:1 calls begins March 2016 for 12 months
  - California submitted a draft “driver diagram” and outlined improvement areas with focus on improvement metabolic monitoring in managed care plans



## Actions to Combat Prescription Opioid Abuse

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- CMS teleconference “Medicaid State Agencies Pharmacy Programs’ Latest Strategies to Combat the Opioids Epidemic”
  - September 29, 2016, 8:30 A.M.-9:30 A.M. PDT.
  - Presentation by three states



## Actions to Combat Prescription Opioid Abuse (cont.)

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- Selected California's best practices
  1. San Francisco Department of Public Health's academic detailing on prescribing naloxone
    - [Academic Detailing Naloxone](#)
  2. Partnership Health Services: Managing Opioids Safely Toolkit [Opioid Safety Toolkit](#)
  3. California Health Care Foundation's new tools:
    - [CHCF opioid resources](#)



## 2018 CMS DUR Annual Report Planning Committee

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- Some states are testing the feasibility of using the 2015 DUR annual report template for managed care health plans
- The effective date of inclusion of managed care health plan DUR data is Federal Fiscal Year 2018 (October 1, 2017-September 2018)
- CMS is convening a 2018 annual report planning committee to seek feedback from state Medicaid DUR programs
  - California is a member of the planning committee
  - Planning Committee's first conference call is scheduled in November 2016



## DHCS Quality Strategy Annual Update

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- New this year is a web-based QI Evaluation System for the annual survey
  - More efficient and easier to update existing QI projects and/or add new ones
  - New questions added to address health disparities
  - Opportunities to include DUR studies in DHCS Quality Strategy



## 2016 Child Core Set Measures

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- The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)
  - CHIPRA required HHS to identify and publish a core measure set of children's health care quality measures for voluntary use by State Medicaid and CHIP programs.
  - Measure Applications Partnership (MAP), convened by National Quality Forum (NQF) provides input to HHS, including annual recommendations for revising measures in the Child Core Set and identifying high-priority measure gaps.
  - MAP supported the 2015 Child Core Set measures for continued use. In addition, MAP recommends consider up to six measures for phased addition.
  - New measure include Use of Multiple Concurrent Antipsychotics in Children & Adolescents (APC)
  - 2016 [Child Core Set Measures](#)



## 2016 Adult Core Set Measures

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- The Affordable Care Act (Section 1139B) requires the Secretary of HHS to identify and publish a core set of health care quality measures for 2016 adult Medicaid enrollees.
- [2016 Adult Core Set Measures](#)
- New measures added include:
  - Diabetes Screening for People with Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)
  - Use of Opioids at High Dosage (OHD)



## Academic Detailing Conference Working Agenda

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- Conference date: October 20, 2016
- Conducted a survey in July 2016 to seek feedback on potential clinical topics for presentations
  - Clinical topics include: opioids use and misuse, naloxone for opioids overdose, diabetes
  - Program topics include: best practices examples, team based care, developing a business case
- Aim to finalize the agenda and presentations by October 1, 2016



# Questions?

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Email:

[Pauline.Chan@dhcs.ca.gov](mailto:Pauline.Chan@dhcs.ca.gov)

