Notice is hereby given that the Medi-Cal DUR Board will conduct a public meeting on Tuesday, May 16, 2017, at the following location:

Department of Health Care Services
1500 Capitol Avenue
Training Rooms A+B
Sacramento, CA 95814

Medi-Cal Drug Use Review Board
Meeting Agenda
May 16, 2017
9:30 AM-12:30 PM

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<th>Report Type*</th>
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<td>C</td>
<td>1. Welcome/Introduction</td>
<td>Pauline Chan, RPh, MBA</td>
<td>930-935</td>
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<td>A</td>
<td>2. Call to Order/Review and Approval of Previous Minutes from February 21, 2017</td>
<td>Robert Mowers, PharmD</td>
<td>935-940</td>
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<td>3. Old Business</td>
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<td>A</td>
<td>a. Review of Action Items from Previous Board Meeting:</td>
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<td>i. Update on Additive Toxicity Alert</td>
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<td>R/A/D</td>
<td>a. Board Activities</td>
<td>DUR Board</td>
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<td>b. DUR Annual Report to CMS – FFY 2016</td>
<td>Pauline Chan, RPh, MBA and Hannah Orozco, PharmD</td>
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e. Review of Physician Administered Drugs (PADs): 4Q2016

f. Prospective DUR
   i. Review of DUR Alerts for New GCNs: 1Q2017
   ii. Review: Quetiapine + Ingredient Duplication (ID) Alert
   iii. Review: Late-Refill (LR) Alert
   iv. Update: Additive Toxicity (AT) Alert

g. Review of DUR Educational Outreach to Providers
   i. Proposal: Early Refill
   ii. Proposal: Fluoroquinolones

h. Retrospective DUR
   i. Review: Over-the-Counter Drugs
   ii. Review of DUR Publications
      i. DUR Alert (April, 2017): Adult Immunizations
      ii. DUR Bulletin (April, 2017): Proton Pump Inhibitors
      iii. Discussion/Recommendations for Future Bulletins

j. Pharmacy Update
   i. Medicaid DUR State Comparison FFY 2015
   ii. Pharmacy Policy Change: Meperidine
   iii. Pharmacy Policy Change: Opioid Quantity Limits
   iv. MMWR: Initial Prescription Opioids and Long Term Opioid Use
   v. FDA Drug Safety Communications: Codeine & Tramadol
   vi. DHCS Quality Improvement Strategy 2017
   vii. Academic Detailing Conference/Resources

5. Public Comments

6. Consent Agenda

a. Meeting feedback

b. Next meeting: September 19, 2017 (9:30 AM -12:30 PM)
   DHCS Training Rooms A+B
   1500 Capitol Avenue
   Sacramento, CA 95814

c. Proposed DUR Board Meeting Dates for 2017/2018:
   Tuesday, November 21, 2017
   Tuesday, February 20, 2018
   Tuesday, May 15, 2018
   Tuesday, September 18, 2018
   Tuesday, November 20, 2018

7. Adjournment

* 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).
## MEDI-CAL DRUG USE REVIEW BOARD MEETING MINUTES
Tuesday, February 21, 2017
9:30 a.m. – 12:30 p.m.

### Location:
Conduent
840 Stillwater Road, Mendocino Room
West Sacramento, CA 95605

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| **1) WELCOME/INTRODUCTION** | • The meeting was called to order by the Chair of the Board, Dr. Robert Mowers.  
• Board members present: Drs. Timothy Albertson, Patrick Finley, Janeen McBride, Robert Mowers, Randall Stafford, Marilyn Stebbins, and Andrew Wong.  
• Board members absent:  
• Board members and attendees introduced themselves.  
• Pauline Chan, RPh was present from DHCS Pharmacy Benefits Division. Also present from DHCS were Julia Logan MD, MPH, Ash Amarnath, MD, and Thurman Frierson.  
• Hannah Sandy, PharmD (Conduent) introduced herself and explained that the Department of Health Care Services (DHCS) Fiscal Intermediary (FI) for the Medi-Cal program, formerly Xerox State Healthcare, LLC (Xerox), is operating under a new company name, “Conduent.” Operations and interactions with the Medi-Cal Drug Use Review Board (the “Board”) are not impacted by this name change.  
• Dr. Sandy also reminded the group that future DUR Board meeting announcements and links to materials will only be sent out to the public through the Medi-Cal Subscription Service (MCSS). She let everyone know that MCSS is here in person to sign people up for these DUR updates after the meeting and can answer any questions. Finally, Dr. Sandy reminded everyone that the DUR Board meeting is being recorded and reminded everyone to sign the attendance sheet. |
| **2) CALL TO ORDER/REVIEW AND APPROVAL OF NOVEMBER 2016 MINUTES** | The Board reviewed the November 15, 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.  
**ACTION ITEM:** Incorporate Dr. Wong’s edits into the minutes and post to the DUR website. |
| **3) OLD BUSINESS** | a. Review of Action Items from Previous Board Meeting:  
   i. Dr. Stafford’s Buprenorphine Study: Dr. Stafford announced that James Gasper, PharmD, BCPP (DHCS) and Jane Ballantyne, MD, FRCA (University of Washington) were both added to the study team as co-investigators.  
   ii. Updates to Section 25 of the DUR Manual: Amanda Fingado, MPH (UCSF) reported that the recommended edits to Section 25 were accepted and the updated DUR manual has posted to the DUR website.  
   iii. Review of HCV medication utilization (November 2017): Ms. Fingado reported that she will report on this in more detail later in the meeting.  
   iv. Prospective DUR: Additive Toxicity (AT) Alert: Ms. Fingado reported that she will report on this in more detail later in the meeting.  
   v. Updated utilization data – CNS Depressants: Ms. Fingado reported that she will report on this in more detail later in the meeting. |
4) NEW BUSINESS

a. Board Activities:
   i. Review of Board Goals and Objectives – Dr. Mowers presented the following DUR Board Goals for the next two years (2017-2018):
      - Implement the DUR requirements of Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)
      - Revise the DUR Bylaws
      - Promote dialogue, collaboration, and recommend best practices in pharmacy utilization management on drugs that are commonly used in both Medi-Cal fee-for-service and managed care
      - Establish a plan to systematically review prospective DUR alerts
      - Establish a plan to systematically develop retroactive DUR criteria
      - Conduct studies to evaluate various methods in the design of “dear doctor” letters
      - Conduct learning collaborative with managed care health plans and other agencies to promote best practices using academic detailing
      - Align DUR board goals with DHCS Quality Strategy and include at least one DUR measure in the DHCS Quality Strategy

b. Pharmacy Update presented by Pauline Chan
   i. Opioid Quantity Limits: Ms. Chan reported that for FFY 2015, a total of 35 DUR programs have set quantity limits for short-acting opioids and 39 DUR programs have set quantity limits for long-acting opioids. She reported that in comparison to the other programs, California’s policies are somewhat unique in that they do not have established 30-day supply limits, daily unit limits, or varying days’ supply by drug. Ms. Chan then briefly summarized important resources available through the California Health Care Foundation website at: http://www.chcf.org/publications/2016/06/changing-health-plans-opioid, including three successful case studies targeting opioid overuse from Partnership HealthPlan of California, Blue Shield of California, and Kaiser Permanente Southern California. Recommendations for action included quantity limits and a multifaceted approach to combating opioid overuse.
   ii. Psychotropic Drug Age Restrictions: Ms. Chan reported that effective 1/1/2017, age restrictions have been added to all psychotropic drugs, based on the FDA-approved minimum age for each drug. This addition is based on recommendations from the state auditor’s report State 2015-131 on California’s foster care system, the text of which is available at: https://www.auditor.ca.gov/pdfs/reports/2015-131.pdf. If the beneficiary does not meet the FDA-approved minimum age, an approved Treatment Authorization Request (TAR) will be needed in order to complete the transaction. Ms. Chan also stated that Medi-Cal will be monitoring the impact of this new restriction.
   iii. DUR Program Review 2016: Ms. Chan reviewed the achievements of the DUR Program during calendar year 2016. Highlights included the following:
      - Dr. Robert Mowers began two-year term as DUR board chair
      - Dr. Patrick Finley began two-year term as DUR vice-chair
      - Dr. Marilyn Stebbins co-authored a white paper on Comprehensive Medication Management (CMM), sponsored by the California Department of Public Health
      - Initiated a new project: Academic Detailing, “kick off” conference in October
      - Endorsed a new Buprenorphine Study led by Dr. Randall Stafford
      - Dr. Hannah Sandy joined as new DUR pharmacist from Conduent (formerly Xerox)
      - Published six educational articles
      - Mailed a total of 825 provider letters on five educational DUR topics
      - Continued outreach with board representation at state-wide opioid workgroup and Psychotropic Quality Improvement Project (QIP)
      - DUR team represented California Medi-Cal in CMS Antipsychotic Drugs for Children (ADC) Affinity Workgroup
      - DUR team presented a poster at the American Drug Utilization Review Society (ADURS) annual meeting
encouraged attendees to read the summary report, specifically focusing on how California compares with the rest of the Medicaid programs and how California could learn from other programs to improve DUR. Ms. Chan reminded the Board that this summary report was for FFY 2015, which covered October 1, 2014 through September 30, 2015.

Dr. Stebbins wondered how it is determined if a DUR Board will set criteria or be advisory, like in California. Ms. Chan explained that each state is bound by legislation that regulates the DUR Board, including California. States may have different regulations that allow a different level of involvement. Dr. Stebbins agreed there is a lot of variability across states.

Ms. Chan pointed out that many states have programs in place to perform educational interventions at the pharmacy level. She stated that this is something California would like to pursue for FFY 2016. Dr. Stafford asked if there were any barriers that might impact sending letters to pharmacies. Ms. Fingado stated that currently a report is sent to DHCS with the top pharmacies by alert volume, which includes the percentage of paid claims with a DUR alert that are overridden by the pharmacy. Ms. Fingado stated that there had been discussion about how to use these data to begin interventions at the pharmacy level and that this was a goal for FFY 2016.

Dr. Stebbins asked about how DUR alerts could be applied to physician-administered drugs (PADs), which some states indicate they are doing. An audience member (Lisa Ashton, PharmD, Johnson & Johnson) stated that this could be explained by states with specialty pharmacy programs that handle the purchase of PADs.

Dr. Finley stated that the comparison report is an important document that we should review more closely. Dr. McBride stated that she thought most managed care plans in California may be doing some of the actions in the report that the fee-for-service group may not be doing. Dr. Stebbins asked if this might make fee-for-service look bad if the managed care plans are taking action and fee-for-service is not. Ms. Chan stated that when we complete the report, we complete the report using all sources of information for the fee-for-service program. Ms. Chan gave the example of the lock-in program, which is not overseen by the DUR program, but is required by Title 22 and is administered by Audits and Investigations division. The Annual Report to CMS includes a description of the lock-in program, as it encompasses fee-for-service beneficiaries.

v. DUR and Medi-Cal Managed Care Final Rule: Ms. Chan reported that the Medicaid and CHIP Managed Care Final Rule (CMS 2390-F) was effective as of July 5, 2016. Implementation is phased in over a three-year period, and states need to ensure that managed health care plan contracts starting on or after July 1, 2017 include language on DUR requirements. The DUR Annual Report to CMS for FFY 2018 will include both Medi-Cal FFS and Managed Care plans. Ms. Chan reported that the details are still being worked out, but will be finalized soon.

vi. Quality Strategy 2016 Updates (NQF, CMS, DHCS): Ms. Chan stated that the DUR program will be following the quality strategies of the National Quality Forum (NQF), CMS, and DHCS. Each of these quality strategies contain similar aims, goals, and priorities and will set the framework for the DUR program. The DHCS Quality Strategy Report is updated and released annually and includes progress and status of Quality Improvement Projects. Ms. Chan stated that the DUR program will submit a project for continuous tracking and trending in this report.

vii. 2017 Medicaid Core Measures (Child & Adult): Ms. Chan reported that the 2017 core measures were announced by CMS on December 5, 2016. While reporting is voluntary, for FFY 2015, all states and the District of Columbia reported at least one child core set measure, and 41 states voluntarily reported at least 12 (of 23) measures, with a median number of reported measures of 16. For adults, 39 states reported core measures, with the median number of reported measures also 16. Ms. Chan stated that one of the pharmacy-related measures California reported on was post-partum contraceptive care.

Dr. Finley asked how many measures California reported on in FFY 2015 and what is
meant by “postpartum contraceptive care”. Ms. Chan said she would have to check. Julia Logan, M.D., M.P.H., the Chief Quality Officer for DHCS, stated that the measure looked at utilization rates of long-acting reversible contraception (LARC) in the postpartum period. Dr. Logan reported that this measure was being evaluated as part of a two-year grant from CMS to look at contraception. Dr. Logan also clarified that there were 18 adult core set measures looked at in California and that no grants were received for evaluating pediatric measures.

viii. Expanding Pharmacy Practice: Ms. Chan summarized an informational bulletin from CMS that was sent on January 17, 2017 regarding the expanded pharmacy scope of practice, which allows pharmacists to dispense drugs prescribed independently, under collaborative practice agreements, or through other predetermined protocols. Specific examples that fall under the expanded scope of practice include: naloxone, nicotine replacement therapy, immunizations, and emergency contraception. Dr. Stebbins pointed out that the state legislation includes both emergency contraception and hormonal contraception. Ms. Chan stated that CMS encourages states to consider using methods to promote access, particularly to those drugs that can help address priority public health issues.

ix. ADC Affinity Workgroup: Ms. Chan shared the driver diagram submitted to the CMS Antipsychotic Drugs in Children (ADC) Affinity Workgroup. She reported that the ADC Affinity Workgroup was a 12-month program, which will be ending in March 2017. She reminded everyone that our small test of change for this workgroup will be the final outcomes of the DUR mailing to providers aimed at improving metabolic monitoring rates for children and adolescents who are taking antipsychotic medications

x. Psychotropic Medications Workgroup: Ms. Chan updated the group with the latest information from the Improving Psychotropic Medication for Children and Youth Quality Improvement Project, including that the Clinical, Data and Technology, and Youth & Family Education Workgroups have completed their 2016 deliverables. The QIP transitions to the Implementation Workgroup include an annual revision of the California guidelines, ongoing data sharing, and ongoing data collection and analyses with quarterly posting on a public website. She described both the global data sharing agreement and the psychotropic medication data sharing agreement and showed the most recent data available via the California Child Welfare Indicators Project (CCWIP), a collaborative venture between the University of California at Berkeley (UCB) and the California Department of Social Services (CDSS). Data are posted on the CCWIP website available at: http://ccwip.uc berkeley.edu/ucb_childwelfare/.

xi. Academic Detailing Webpage & Resources: Ms. Chan stated that the information from the first academic detailing conference at DHCS is available on the DUR website at: http://files.medi-cal.ca.gov/pubsdoco/dur/dur_wnup.asp. She reminded the group that this is an ongoing collaboration.

xii. HIV Surveillance, Prevention & Care Plan: Ms. Chan summarized California’s HIV Plan, available at the California Department of Public Health (CDPH) website at: http://www.cdph.ca.gov/programs/aids/Pages/GettingtoZeroCalifornia.aspx. She stated there are specific pharmacy-related strategies included in the plan and that the DUR Board could play a role.

xiii. Improving Access to Pre-natal Vitamins: Ms. Chan reported that there are approximately 500,000 Medi-Cal births throughout the state each year. Based on Medi-Cal pharmacy claims data, between July 1, 2015, and June 30, 2016, the numbers of unique Medi-Cal beneficiaries with a paid claim for pre-natal vitamins with folic acid were only 98,302 beneficiaries in the fee-for-service program and 122,779 beneficiaries in Medi-Cal managed care. There are opportunities to improve access to pre-natal vitamins and opportunities to collaborate with CDPH through outreach programs.

c. Quarterly Report – 4Q2016 (October – December 2016): Ms. Fingado reported that a comparison of 2016 Q4 to the prior-year quarter showed a 9% decrease in total utilizing beneficiaries and an 13% decrease in total paid claims. When overall utilization from 2016 Q4 was compared to the prior quarter there were 3% decreases in both total utilizing beneficiaries and total paid claims. In 2016 Q4, all age groups except the 0-12 year age group posted decreases in total utilizing beneficiaries and total paid claims in comparison to the prior quarter. Historically, this age group posts increases in both utilizing beneficiaries
and total paid claims from Q3 to Q4, skewed heavily by drugs related to cold and flu season, which peaks in California during in late Q4 and early Q1.

In addition, Ms. Fingado reported that two years after being re-classified as a Schedule II controlled substance (effective October 6, 2014), HYDROCODONE/ACETAMINOPHEN continues to post decreases in total paid claims in comparison to the prior quarter (decreased by 12%) and to the prior-year quarter (decreased by 24%).

d. Review of Physician Administered Drugs (PADs) – 3Q2016 (July – September): Ms. Fingado showed a summary of paid claims for physician-administered drugs for the 3rd quarter of 2016, which includes paid claims with dates of services between July 1, 2016, and September 30, 2016. 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 per utilizing beneficiary. Ms. Fingado reported increases in both total utilizing beneficiaries (a 28% increase) and total paid claims (a 19% increase) from 2Q2016 to 3Q2016 in the category “PHYSICIAN ADMINISTERED DRUG – NDC NOT REQUIRED,” which can be attributed to large increases in the influenza vaccine starting in September 2016. Within this same category, Ms. Fingado pointed out decreases in both total utilizing beneficiaries (a 7% decrease) and total paid claims (an 8% decrease) from 3Q2015 to 3Q2016. Ms. Fingado stated that this decrease is in line with the 9% decrease in utilizing fee-for-service beneficiaries during this same time period.

e. Prospective DUR reports were presented by Amanda Fingado

i. Review of DUR Alerts for New GCNs in 4Q2016 (October – December 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 thirteen GCNs:
     - GCN #076640: MORPHINE SULFATE IN 0.9 % NAACL - Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCNs #076571 and #076641: KETOROLAC/NORFLURANE/HFC 245FA - Drug-Pregnancy (PG)
     - GCN #076610: CHORIONIC GONADOTROPIN, HUMAN - Drug-Pregnancy (PG)
     - GCN #076650: SUMATRIPTAN SUCC/NAPROXEN SOD - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCN #076612: LEVONORGESTREL - Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCN #076654: DICLOFENAC SODIUM - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCN #076746: DICLOFENAC SODIUM/CAPSAICIN - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCN #076707: CLOPIDOGREL BISULFATE - Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
     - GCN #075151: MIDAZOLAM HCL/PF - Drug-Pregnancy (PG)
     - GCN #076825: FENOPROFEN CALCIIUM, DIHYDRATE - Drug-Pregnancy (PG)
     - GCN #073919: INSULIN DEGLUDEC/LIRAGLUTIDE - Drug-Pregnancy (PG)
     - GCN #076873: KETOROLAC TROMETHAMINE - Drug-Pregnancy
• GCNs #076904: DICLOFENAC SOD/KINESIOLOGY TAPE - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
• GCNs #063133 and #064736: METHOXY PEG-EPOETIN BETA - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Drug-Age (PA), 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: Additive Toxicity (AT) Alert
• Ms. Fingado reported that in the Medi-Cal System, the AT alert is generated when a patient reaches a threshold of four active prescriptions for any combination of drugs in specified therapeutic classes. Section 35 of the Medi-Cal DUR Manual specifies that the AT alert should be on for Scheduled pain medications and/or psychotropics. A review of the AT alert showed inconsistencies between drugs (and individual GCNs) that appear on the Medi-Cal AT target drug list and drugs with the AT alert turned on in the Medi-Cal prospective DUR system:
  o Some drugs appear in the DUR manual on the AT target drug list (TDL) but the AT alert is not turned on in the system
  o Some drugs that are Scheduled pain medications and/or psychotropics do not appear on the AT target drug list and/or do not have the AT alert turned on in the system

• Ms. Fingado also reported that on August 31, 2016, the U.S. Food and Drug Administration (FDA) announced that it will require class-wide changes to drug labeling, including patient information, to help inform health care providers and patients of the serious risks associated with the use of certain opioid medications in combination with benzodiazepines and other central nervous system (CNS) depressants. At the November 15, 2016 DUR Board meeting, it was suggested that by updating the AT alert to focus on opioids, benzodiazepines, and other CNS depressants, the AT alert could be an effective tool to help providers identify patients who may be at high-risk for serious adverse events.

• Ms. Fingado recommended:
  o Turning on or keeping on the AT alert for all drugs on the list provided by the FDA.
  o Keeping on the AT alert for current drugs on with the AT alert on that are considered either Scheduled pain or psychotropic medications, regardless of whether they appear on the list provided by the FDA.
  o Turning off the AT alert for drugs either not approved by the FDA, drugs taken off the market in the United States, and/or all drugs not on the list provided by the FDA nor Scheduled pain or psychotropic medications.

There was much discussion by the Board as to the best way to move forward with these recommendations. Dr. Albertson recommended that we be consistent over different categories of drugs, although he thought we didn’t need to turn on ALFENTANIL, REMIFENTANIL, and SUFENTANIL. Ms. Chan commented that the target drug list may need to be revised. Ms. Fingado suggested some alerts could be turned on in test mode to evaluate the alert burden before going live with turning on all the alerts in Table 2. Dr. Albertson said he liked that idea. Dr. Mowers made a motion to turn all the alerts on in Table 2 in test mode and bring the results back for discussion at a future meeting. The motion was approved.

**ACTION ITEM**: The DUR Board recommendation to turn on the Additive Toxicity Alert in test mode for all drugs that appear on the FDA list of opioids, benzodiazepines, or other CNS depressants will be submitted to DHCS.
There was a motion made by Dr. Finley to work offline on the list of drugs in Table 3 and revisit at the next DUR Board meeting in May. Dr. Stafford seconded the motion and Dr. Wong stated he is interested in working with Dr. Finley on the list of drugs.

**ACTION ITEM:** The DUR Board recommendation to review additional drugs for the Additive Toxicity Alert that do not appear on the FDA list of opioids, benzodiazepines, or other CNS depressants will be submitted to DHCS.

Regarding Table 4, there was a motion to turn off the AT alert for METHOTRIMEPRAZINE, METHOXY PEG-EPOETIN BETA, and TESTOSTERONE only. The motion carried without further discussion.

**ACTION ITEM:** The DUR Board recommendation to turn off the Additive Toxicity Alert for METHOTRIMEPRAZINE, METHOXY PEG-EPOETIN BETA, and TESTOSTERONE will be submitted to DHCS.

### f. Review of DUR Educational Outreach to Providers

#### i. Update: Buprenorphine Letter

- Ms. Fingado presented information about the target populations for this intervention. She described that the top prescribers (by total quantity prescribed) of opioids in the Medi-Cal fee-for-service program between October 1, 2015 and September 30, 2016 were cross-referenced to the list of California providers with a current waiver to provide buprenorphine treatment. A total of 100 of the top prescribers of opioids without a current buprenorphine waiver were sent a letter with more information about buprenorphine training. A second mailing was completed with the top 100 prescribers (by total number of patients) of buprenorphine in the Medi-Cal program between October 1, 2015 and September 30, 2016 were sent a letter 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.
- All packets were mailed to providers on November 11, 2016. A total of 24 undeliverable letters were re-sent to different addresses on January 30, 2017.
- Ms. Fingado reported that thus far, a total of 25 prescribers (out of 200 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 13% and a total of 38 prescribers (out of 200 unique prescribers) returned their surveys, for a provider response rate of 19%.
- Of the 38 surveys that were returned, a total of 21 surveys (55%) indicated that the provider found the mailing very useful, a total of 13 surveys (35%) indicated that the provider found the mailing somewhat useful, and 3 surveys (8%) indicated that the provider did not find the mailing useful.
- Ms. Fingado summarized the written comments received thus far from top opioid prescribers (n=8) and top buprenorphine prescribers (n=14). She reminded the group that as stated in the original proposal, the following outcome variables will need to be assessed at later time points, as medical claims data become available:
  - 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 (primary outcome).
  - The number of providers contacted who complete the training and applied for a waiver (secondary outcome).
  - The percentage change (by total quantity prescribed) of total opioid prescribing in the Medi-Cal fee-for-service population, by individual provider among providers contacted (secondary outcome).

#### ii. Update: Metabolic Monitoring 2016 Letter

- Ms. Fingado reported that the study population identified when writing the policy impact report was used to identify Medi-Cal fee-for-service (FFS) beneficiaries in need of metabolic testing. This initial study population was comprised of a total of 2,272 children and adolescents who met the following criteria:
Between 1 and 17 years of age (between January 1, 2015 and December 31, 2015)
- Had at least two paid claims for an antipsychotic medication between January 1, 2015 and December 31, 2015
- Did not have a paid claim for either a HbA1C/glucose or LDL-C/cholesterol test between January 1, 2015 and December 31, 2015

For the mailing, eligibility criteria was re-reviewed for each of these beneficiaries to ensure they remained continuously enrolled in the Medi-Cal fee-for-service program between January 1, 2016 (the day after the original data pull for the DUR educational bulletin) and September 30, 2016. Further inclusion/exclusion criteria for beneficiaries to be included in the study population for the mailing included:
- Beneficiaries < 18 years of age through November 30, 2016
- Beneficiaries with ≥ 2 paid claims for an antipsychotic medication between January 1, 2016 and September 30, 2016 (≥ 4 paid claims total between January 1, 2015 and September 30, 2016)
- Beneficiaries currently taking an antipsychotic medication (a paid claim with a days supply extending past July 31, 2016)
- Did not have a paid claim for either an HbA1C/glucose or LDL-C/cholesterol test between January 1, 2016 and September 30, 2016
- Patient/prescriber combinations were excluded if they were already mailed letters in 2015 and a patient survey was received by the DUR program

Ms. Fingado stated that a total of 578 beneficiaries from the original cohort of 2,272 met the above inclusion/ exclusion criteria. There were two cases where a beneficiary had two prescribers prescribing different medications concurrently so both prescribers were included in the mailing. Twenty-five patient/prescriber combinations were included in the 2015 mailing and had surveys received, although only 24 were excluded for this mailing, as one survey stated that that prescriber had no knowledge of the patient. Eleven additional prescriptions were filled from that prescriber since the 2015 mailing, so this patient/prescriber combination was included again. A total of 361 prescribers were identified for educational outreach letters. All packets were mailed to providers on November 11, 2016. A total of 67 undeliverable letters were re-sent to different addresses on January 30, 2017.

Ms. Fingado reported that thus far, a total of 68 prescribers (out of 361 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 19% and a total of 103 prescribers (out of 361 unique prescribers) returned their surveys, for a provider response rate of 29%.

Of the 185 patient surveys that were returned, a total of 162 surveys (88%) 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=107; 58%)
- “I have reviewed the information and will continue without change” (n=47; 25%)
- “however, has not seen me recently” (n=8; 4%)
A total of 23 surveys (12%) indicated that the patient was not currently under their care and a total of 88 patient surveys (46%) contained written comments from providers, with the majority of comments discussing lab testing recently completed or ordered.

Ms. Fingado reminded the group that as stated in the original proposal, the following outcome variables will be assessed at later time points, as medical claims data become available:
- 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 (primary outcome).
- The percentage of patients with additional paid claims for antipsychotic medications within 6 months following the mailing of the intervention letter (secondary outcome).

iii. Update: Asthma 2017 Letter
- Ms. Fingado reported that pharmacy and medical claims were used to identify Medi-Cal FFS beneficiaries with 1) at least four or more dispensing events for asthma rescue medications in 2016 2) no paid claims for an outpatient visit in which asthma was one of
the listed diagnoses between October 1, 2015 and January 31, 2017; and 3) an asthma medication ratio (AMR) < 0.50 during the measurement year. Further inclusion criteria were continuous eligibility in Medi-Cal FFS between October 1, 2015 and January 31, 2017 (16 months prior to the mailing) and a paid claim for an asthma medication between November 1, 2016 and January 31, 2017 (90 days prior to the mailing).

Exclusion criteria for the educational DUR educational outreach to providers included 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. A total of 528 beneficiaries with asthma medications prescribed by 661 different providers met all of the above inclusion/exclusion criteria.

- Ms. Fingado reported that on February 17, 2017, all 661 prescribers 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
  - List of patients, including patient name, date of birth, history of paid pharmacy claims for asthma rescue and asthma controller medications, history of emergency department visits and inpatient hospitalizations where the primary diagnosis or secondary diagnosis was listed as asthma (dates of service between January 1, 2016, and December 31, 2016)
  - Medi-Cal DUR article on asthma quality-of-care
  - Patient survey (one per patient)

- Ms. Fingado stated that a total of 578 beneficiaries from the original cohort of 2,272 met the above inclusion/exclusion criteria. There were two cases where a beneficiary had two prescribers prescribing different medications concurrently so both prescribers were included in the mailing. Twenty-five patient/prescriber combinations were included in the 2015 mailing and had surveys received, although only 24 were excluded for this mailing, as one survey stated that that prescriber had no knowledge of the patient. Eleven additional prescriptions were filled from that prescriber since the 2015 mailing, so this patient/prescriber combination was included again. A total of 361 prescribers were identified for educational outreach letters. All packets were mailed to providers on November 11, 2016. A total of 67 undeliverable letters were re-sent to different addresses on January 30, 2017.

- Ms. Fingado stated that the rate of undeliverable packets and the provider response rate will be calculated 90-days after the mailing. Provider survey responses will also be collected and presented in aggregate. In addition, the following primary outcome variable will be reported in a future update:
  - The percentage of beneficiaries with an outpatient visit in which asthma was one of the listed diagnoses within 90 days following the packet mailing date in a subgroup of continuously eligible Medi-Cal FFS beneficiaries.

- Ms. Fingado also reported that the following secondary outcome variables will be assessed for the 12 months following the packet mailing date in a subgroup of continuously eligible Medi-Cal FFS beneficiaries:
  - Total reimbursement paid to pharmacies for all asthma-related pharmacy claims
  - Percentage of beneficiaries with an AMR ≥ 0.50 (among beneficiaries still taking any medication for asthma)
  - The net change in AMR by individual utilizing beneficiary (among beneficiaries still taking any medication for asthma)
  - Rate of emergency department visits where the primary diagnosis is asthma
  - Rate of inpatient hospitalizations where the primary diagnosis is asthma

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

- **i. Review of Retrospective DUR Criteria: Proton-Pump Inhibitors**
  - The DUR Board had expressed an interest in finding out more information about the utilization of PROTON-PUMP INHIBITORS in the Medi-Cal fee-for-service population. Dr. Lynch reported that the United States Food and Drug Administration (FDA) has issued several safety alerts for PPIs dating back to 2007 and while recent pharmacy claims data from the Medi-Cal Fee-for-Service (FFS) program show that PPIs recently
dropped out of the top 20 drug therapeutic categories (by the percentage of utilizing beneficiaries with a paid claim), PPIs remain one of the top 10 most utilized over-the-counter medications in the FFS program. At the DUR Board meeting on September 20, 2017, the DUR Board requested a retrospective DUR review of the entire class of PPIs. Dr. Lynch reported that this review also includes a review of the class of H2 receptor antagonists as well, as both medications work by blocking and decreasing the production of gastric acid.

- Dr. Lynch presented utilization data for all paid claims for PROTON-PUMP INHIBITORS in the Medi-Cal fee-for-service program between November 1, 2015, and October 31, 2016. Dr. Lynch reported that when a date of service restriction was added to omeprazole in April 2016, use went from approximately 5,000 beneficiaries to close to zero beneficiaries within a month. She noted a slight increase in utilizing beneficiaries with a paid claim for other proton-pump inhibitors and H2 antagonists for the next two months, but after June 2016, utilization for these drugs went back to previous levels. In order to account for the shift in the Medi-Cal FFS population and to evaluate the change in utilization data over time, the change in utilizing beneficiaries was calculated. Overall use of PPIs decreased by 40% during the measurement year, while the population decreased by only 6%. Among the 65 years and older age group, the decline was even greater (a decrease of 55%, compared with a population decrease of 8%). Use of H2 antagonists, by comparison, remained relatively parallel with the overall decrease in total utilizing beneficiaries (decreases of 7% and 6%, respectively), but showed a much greater decrease in the 65 years and older population, suggesting that overall use of these medications is decreasing in this population.

- Dr. Lynch recommended the following to the DUR Board for their consideration:
  o Review and discuss the utilization data for the PPI and H2 antagonist medications and determine if there is a need for further evaluation.
  o Discuss potential areas within this class of medications that might merit a DUR educational alert or bulletin, for example, information regarding potential adverse events related to the use of PPIs, as well as current treatment recommendations. Given the association with kidney disease and low magnesium levels, rates of serum creatinine and magnesium levels monitoring could be calculated for FFS beneficiaries.
  o Discuss potential benefits of DUR educational outreach to providers regarding PPIs. Different subgroups for consideration could include the following:
    ▪ Prescribers with patients 65 years of age and older with paid claims for PPIs
    ▪ Prescribers with infant patients with paid claims for PPIs
    ▪ High-volume prescribers of PPIs
    ▪ Prescribers with patients with > 180 days of paid claims for PPIs and no paid claims for serum creatinine and magnesium monitoring tests within two years

Dr. Stafford recommended an evaluation of those beneficiaries who appear to be chronic users of PPIs and determine whether or not these beneficiaries had experienced a break in PPI use over the past year or not. The Board agreed there would be merit in an educational bulletin on PPIs, including information about tolerance and how to taper/discontinue the use of PPIs.

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

i. DUR Educational Bulletin (February 2017): Fluoroquinolones
  - Dr. Lynch presented a summary of the DUR educational bulletin entitled, “Improving the Quality of Care: Risks Associated with Use of Fluoroquinolones.” This bulletin had the following learning objectives:
    o Review the United States Food and Drug Administration (FDA) labeling changes for fluoroquinolones, including the updated Boxed Warning
    o Describe potential adverse effects associated with use of fluoroquinolones
    o Summarize best practices for responsible prescribing of fluoroquinolones
  - Dr. Lynch provided some background information on fluoroquinolones, which are a class of broad-spectrum antibiotics that are important for treatment of serious
infections, especially those that are hospital acquired and when resistance to other agents is suspected. The Infectious Diseases Society of America, the American Thoracic Society, and other professional organizations recommend fluoroquinolones not be used as first-line therapy. In addition, Dr. Lynch summarized recent FDA actions regarding fluoroquinolones, including the FDA news release in July 2016 regarding labeling changes to enhance warnings of disabling and potentially permanent adverse effects associated with fluoroquinolone use. The FDA concluded that the risks of fluoroquinolones generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections, with potential adverse effects including tendinitis, tendon rupture, peripheral neuropathy, confusion, and hallucinations.

- A review of the Medi-Cal fee-for-service data showed a total of 50,843 beneficiaries had at least one paid pharmacy claim for a fluoroquinolone medication between December 1, 2015 and November 30, 2016. Dr. Lynch reported that medical claims data were reviewed to determine if the indication was acute sinusitis (19%), acute bronchitis (10%), or uncomplicated urinary tract infections (39%). Based on these data, it appears that approximately 68% of fluoroquinolone use during the measurement year appeared to be potentially inappropriate based on the new FDA recommendations. Dr. Lynch stated that the new recommendations overlapped with the study period so that there may be reduced inappropriate utilization in subsequent months.

- Dr. Lynch stated that clinical recommendations included the following:
  - Providers should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections (UTIs)
  - Providers should discontinue the fluoroquinolone treatment immediately at the first signs or symptoms of any serious adverse reaction
  - Providers should avoid fluoroquinolones in patients who have previously experienced serious adverse reactions associated with fluoroquinolones

Dr. Stafford asked if any other inappropriate use was reviewed beyond these diagnoses. Ms. Fingado stated there were cases without an appropriate diagnosis, but that for the purposes of this bulletin the review focused on the new FDA recommendations, especially given the current pharmacy policy guidelines do allow prescribing of fluoroquinolones for UTIs and for respiratory conditions in beneficiaries 50 years of age and older.

ii. Discussion/Recommendations for Future Educational Bulletins
- The calendar for future DUR educational bulletins was reviewed. The Board did not have any suggested changes or additions/deletions at this time.

<table>
<thead>
<tr>
<th>5) PUBLIC COMMENTS</th>
<th>None.</th>
</tr>
</thead>
<tbody>
<tr>
<td>6) CONSENT AGENDA</td>
<td>The next Board meeting will be held from 9:30 a.m. to 12:30 p.m. on May 16, 2017 in DHCS Training Rooms A+B located at 1500 Capitol Avenue, Sacramento, CA 95814.</td>
</tr>
<tr>
<td>7) ADJOURNMENT</td>
<td>The meeting was adjourned at 12:30 p.m.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action Items</th>
<th>Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorporate Dr. Wong’s edits into the minutes and post to the DUR website.</td>
<td>Amanda</td>
</tr>
<tr>
<td>The DUR Board recommendation to turn on the Additive Toxicity Alert in test mode for all drugs that appear on the FDA list of opioids, benzodiazepines, or other CNS depressants will be submitted to DHCS.</td>
<td>Hannah/Pauline</td>
</tr>
<tr>
<td>The DUR Board recommendation to review additional drugs for the Additive Toxicity Alert that do not appear on the FDA list of opioids, benzodiazepines, or other CNS depressants will be submitted to DHCS.</td>
<td>Amanda/Hannah</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>The DUR Board recommendation to turn off the Additive Toxicity Alert for METHOTRIMEPRAZINE, METHOXY PEG-EPOETIN BETA, and TESTOSTERONE will be submitted to DHCS.</td>
<td>Hannah/Pauline</td>
</tr>
</tbody>
</table>
State of California
MEDICAID DRUG UTILIZATION REVIEW

Centers for Medicare & Medicaid Services
Federal Fiscal Year

ANNUAL REPORT
FEDERAL FISCAL YEAR 2016
This report covers the period
October 1, 2015 to September 30, 2016

Department of Health Care Services
Prepared by

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

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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

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: Conduent (formerly 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 ☐ Other

If the answer above is “Other,” please specify:

___________________________________________________________________________

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.

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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.

________________________________________________________________________
________________________________________________________________________

________________________________________________________________________

We are in the process of streamlining our prospective DUR alerts. Starting in FFY 2017, we will begin 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.

__________________________________________________________________

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.

__________________________________________________________________

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

2. RetroDUR?
   - Yes [x] 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 [x] 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 [x] 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.

<table>
<thead>
<tr>
<th>Number of Generic Claims:</th>
<th>8,479,011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Claims:</td>
<td>12,138,240</td>
</tr>
<tr>
<td>Generic Utilization Percentage:</td>
<td>69.9%</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Generic Dollars:</th>
<th>$327,116,716</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Dollars:</td>
<td>$3,550,676,373</td>
</tr>
<tr>
<td>Generic Expenditure Percentage:</td>
<td>9.2%</td>
</tr>
</tbody>
</table>

VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE

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

☒ Yes ☐ No

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

University of California, San Francisco (UCSF)

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

<table>
<thead>
<tr>
<th>ProDUR Total Estimated Avoided Costs</th>
<th>$229,440,897</th>
</tr>
</thead>
<tbody>
<tr>
<td>RetroDUR Total Estimated Avoided Costs</td>
<td>$0</td>
</tr>
<tr>
<td>Other cost avoidance</td>
<td>$0</td>
</tr>
<tr>
<td>Grand Total estimated Avoided Costs</td>
<td>$229,440,897</td>
</tr>
</tbody>
</table>
4. 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 \( \div \) Total Dollar Amount \( \times \) 100 = \(6.5\%\)

\(\dfrac{229,440,897}{3,550,676,373} \times 100 = 6.5\%\)

5. 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

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 was experiencing 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 was completed in FFY 2016. California law (Health and Safety Code
Section 11165.1) required all California licensed prescribers authorized to prescribe
scheduled drugs to register for access to CURES 2.0 by July 1, 2016 or upon issuance of a Drug Enforcement Administration Controlled Substance Registration Certificate, whichever occurs later. California licensed pharmacists must register for access to CURES 2.0 by July 1, 2016, or upon issuance of a Board of Pharmacy Pharmacist License, whichever occurs later.

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.

__________________________________________________________________

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

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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: There is a maximum quantity of four dosage units per day, regardless of strength. The maximum allowable total daily dose is 48 mg.
2. What are your limitations on the allowable length of this treatment?

☐ 6 months  ☒ 12 months  ☐ No limit  ☐ Other, please explain.

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.

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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 Attachments 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/Hepatitis B treatment drugs;
- Selected alcohol and heroin detoxification and dependency treatment drugs;
- Selected coagulation factors; and
- Selected drugs used to treat psychiatric conditions (including antipsychotics and MAO inhibitors)

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 MCOs are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program and their preferred drug lists (PDLs) are required to be comparable to the Medi-Cal List of Contract Drugs. While all drugs included on the Medi-Cal List of Contract Drugs do not need to be included on the MCOs’ PDLs, comparable means that the drugs on the PDLs must have the same mechanism of action sub-class within all major therapeutic categories of drugs included in the Medi-Cal List of Contract Drugs.

MCOs have their own DUR program that determines the most suitable treatment and prior authorization requirements for their organizations. They do not have the same ProDUR or RetroDUR as the fee-for-service 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 are required to submit Policies and Procedures for DUR and treatment outcomes system to optimize the quality of pharmacy services. The DUR review includes:

- Range and type of drugs taken by members
- General drug utilization patterns of the plan
- List of pharmacy interventions for Quality Improvement Projects (e.g., Asthma, Diabetes, HTN, etc.)
- DUR alert/edit program to detect drug-drug interactions, high dose alert, etc., in order to alert dispensing pharmacy
- Pharmacy service and drug utilization encounter data, including all pharmacy claims, which are provided to the state on a monthly basis

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.

Some of the MCOs have Lock In programs, however not all of the MCOs have verified programs.

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](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 seven educational bulletins and alerts distributed during FFY 2016 include the following:


   Summary: The clinical review described the widespread use of anticholinergic medications for prophylaxis and treatment of antipsychotic-induced EPS, despite systematic reviews and meta-analyses supporting this practice.

   Recommendations:
   1. For patients taking first-generation antipsychotics, prophylactic use of anticholinergic medications to prevent extrapyramidal symptoms should be determined on a case-by-case basis. Patient-specific and medication-specific factors should be considered.
   2. For patients taking second-generation antipsychotics, prophylactic anticholinergic medications are not recommended.
   3. Continued use of anticholinergic medications should be re-evaluated in patients with controlled symptoms every three months.
   4. Older patients and/or persons with high genetic risk of cognitive disorder who use anticholinergic medications are at increased risk of cognitive decline and dementia. Providers should consider discontinuation of anticholinergic medications in these populations.


   Summary: This alert let providers know that as of January 8, 2016, California has updated their prescription drug monitoring program, the Controlled Substance Utilization Review and Evaluation System (CURES) to CURES 2.0. This upgraded database offers a significantly improved user experience and features a number of
added functionalities, including the ability to delegate report queries and new practitioner-identified patient alerts.

Recommendations:
1. All health care practitioners authorized to prescribe or dispense Schedule II – IV controlled substances must sign up and be registered to use CURES by July 1, 2016. Licensed health care prescribers and pharmacists can now request access to the CURES database and validate their credentials entirely online using a secure web browser.


Summary: This alert summarized a United States Food and Drug Administration safety review that found medicines containing saxagliptin and alogliptin may increase the risk of heart failure, particularly in patients who already have heart or kidney disease.

Recommendations:
1. Health care providers should consider discontinuing saxagliptin and alogliptin in patients who develop heart failure. If a patient’s blood sugar level is not well-controlled with their current treatment, other diabetes medicines may be required.


Summary: The clinical review acknowledged that while atypical antipsychotics have many notable benefits compared with their earlier counterparts; their use has been associated with potentially serious adverse metabolic effects, including weight gain, hyperlipidemia, and glucose intolerance and should be prescribed for a specific clinical indication only when the scientific evidence supports the likelihood that benefits will exceed harms.

Recommendations:
1. Health care providers should prescribe atypical antipsychotics for FDA-approved indications.
2. Health care providers should address modifiable risk factors (smoking, obesity, lack of physical activity, unhealthy diet) in patients with mental illness even in the absence of metabolic changes.
3. Health care providers should follow ADA and APA consensus guidelines for baseline assessment and monitoring, including measuring waist
circumference three and six months after starting treatment and annually thereafter.

4. For patients with a worsening metabolic profile, especially weight gain, prescribers should consider switching from an agent with a high risk of metabolic side effects to an agent with low risk.

5. Primary care and mental health providers should communicate frequently for early detection of adverse metabolic effects and to minimize duplicate laboratory monitoring/workup.


Summary: This alert described the warning issued by the U.S. Food and Drug Administration regarding safety risks associated with the use of opioids that are resulting in labeling changes.

Recommendations:
1. Health care providers should discontinue opioid treatment and/or use of the other medicine if serotonin syndrome is suspected.
2. Health care providers should perform diagnostic testing if adrenal insufficiency is suspected. If diagnosed, treat with corticosteroids and wean the patient off of the opioid if appropriate. If the opioid can be discontinued, a follow-up assessment of adrenal function should be performed to determine if treatment with corticosteroids can be discontinued.
3. Health care providers should conduct laboratory evaluations in patients presenting with such signs or symptoms.


Summary: This bulletin reviewed clinical evidence that showed buprenorphine-containing products are an effective first-line treatment for opioid addiction and highlighted pharmacy policy changes within the Medi-Cal program that have improved access to buprenorphine-containing products for beneficiaries.

Recommendations:
1. Health care providers are encouraged to complete the eight hours of required buprenorphine training and apply for a waiver to prescribe buprenorphine.
2. For providers with a current waiver to treat patients with buprenorphine who are not currently treating their allowed maximum number of patients, continue to offer medication-assisted treatment for opioid addiction with buprenorphine to qualified patients.
3. Before writing the first prescription for a buprenorphine-containing product for opioid addiction, providers should 1) assess the patient to verify they meet
the diagnostic criteria for opioid addiction, 2) counsel the patient on the risks and safe storage of buprenorphine products, 3) prescribe a limited amount of medication at the first visit, and 4) anticipate and define a plan for relapse.

4. Pharmacists should ensure that buprenorphine is in stock and available to meet demand for frequent refills.

5. Pharmacists should create a safe and welcoming environment for those patients filling prescriptions for buprenorphine. Be friendly, compassionate, and understanding, particularly in the earlier stages of treatment when patients may be quite uncomfortable.

6. Pharmacists should reach out to patients who do not pick up their refills.

7. 2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus – September 2016

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 2016 in the United States are provided. The summary for 2016 included updates for influenza, Meningococcal, Tdap, Hib, and Rotavirus.

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, with a recommendation against the use of LAIV during the 2016 – 2017 flu season.

2. Health care providers should recommend MenACWY vaccination for 1) all men who have sex with men (MSM) residing in Los Angeles, Orange and San Diego counties and the City of Long Beach, 2) MSM who plan to travel to Los Angeles or Orange counties or the City of Long Beach (to be effective, vaccination should occur at least two weeks prior to travel), and 3) all HIV-infected persons in California.

3. Health care providers should provide Tdap vaccination to pregnant women at the earliest opportunity between 27 and 36 weeks gestation of every pregnancy.

4. Now that there are two rotavirus vaccines, health care providers should recommend the same rotavirus vaccine series be completed with the same vaccine brand but allow for administering mixed vaccine types (using a three-dose series) if the previous dose is unavailable or unknown

The Medi-Cal DUR program also 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 2016, the following two mailings were sent to providers:


   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. 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, there were a total of 380 providers who prescribed prescription opioids > 120 mg MEDD, representing 464 beneficiaries and 1,542 paid claims. 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).

   Outcomes: The overall response rate was 23%. 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. Additional outcomes will be evaluated after 6 months and will be presented to the DUR Board.


   Objectives:
   - 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

Outcomes: A response rate of 12% was noted. 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.
ATTACHMENT 3 – SUMMARY OF DUR BOARD ACTIVITIES

The DUR Board met four times during FFY 2016. The Board members are listed below the summary.

Prospective DUR Criteria Presented

- Drug-Pregnancy (PG) Alert: The Board reviewed prospective DUR alerts for all drugs with a drug-pregnancy alert in order to address inconsistencies in alert status within drug class, and to evaluate drugs with a pregnancy risk category D or X that were found to not have the PG alert on. The Board reviewed all drugs with current pregnancy category D, X and significance level 1 and updated the clinical criteria, as per the DUR manual.

- 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 Drug-Drug Interaction (DD) alerts for 39 GCNs that did not have the DD alert turned on
  - Turn on Ingredient Duplication (ID) and High Dose (HD) alerts for two acetaminophen-containing drugs: GCN 074344 (DIPHENHYDRAM/PE/DM/ACETAMIN/GG) and GCN 074312 (DOXYLAM/PE/DM/ACETAMINOPHEN/GG)
  - Turn off pediatric Low Dose (LD) alert for GCN 067043 (TOPOTECAN), and make alert profile consistent among all TOPOTECAN GCNs
  - Remove BELLADONNA/PHENOBARBITAL from the main target drug list but keep PHENOBARBITAL on the main target drug list
  - Turn on additional alerts for the all FENTANYL GCNs (Drug-Allergy, Drug-Disease, Therapeutic Duplication, Additive Toxicity, Ingredient Duplication, High Dose, and Low Dose)

- Late-Refill Alert (LR): The Board reviewed prospective DUR criteria for the LR Alert, specifically the following inconsistencies between drugs that appear on the Medi-Cal LR target drug list and drugs with the LR alert turned on in the Medi-Cal prospective DUR system:
  - Some drugs appear in the DUR manual on the LR target drug list (TDL) but the LR alert is not turned on in the system
  - Some drugs that are generally not used as maintenance therapy appear on the LR target drug list and/or have the LR alert turned on in the system

The Board recommended the following:
  - Remove the following drugs from the LR target drug list: CELECOXIB, CIPROFLOXACIN, CLONAZEPAM, EPOETIN ALFA, FENTANYL, LEVOFLOXACIN, MEGESTROL, MORPHINE/OPIUM, NITROGLYCERIN, OXYCODONE, PHENOBARBITAL (combination products only), TESTOSTERONE, TRAMADOL, and ZOLOPIDEM
  - Turn off the LR alert for the following drugs (all GCNs): CELECOXIB, CLONAZEPAM, EPOETIN ALFA, MEGESTROL, MORPHINE/OPIUM,
NITROGLYCERIN, PHENOBARBITAL, and TESTOSTERONE
  o Turn on the LR alert for the following drugs (all GCNs): GABAPENTIN and LEVOTHYROXINE.

- 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. GCNs #074293 and #074295: PHENYLEPHRINE/DM/ACETAMINOP/GG - Ingredient Duplication (ID), High Dose (HD)
  2. GCNs #074344, #074459, and #074287: DIPHENHYDRAM/PE/DM/ACETAMIN/GG - Ingredient Duplication (ID), High Dose (HD)
  3. GCNs #072092, #075263, #075264, and #075265: METHYLPHENIDATE HCL - High Dose (HD), Low Dose (LD)
  4. GCNs #073368, #073369, and #073371: PERINDOPRIL ARG/AMLODIPINE BES - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Underutilization (LR), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)
  5. GCNs #074405, #073265, and #074705: DICLOFENAC/CAPSICUM - Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
  6. GCNs #068712 and #070009: FENTANYL CITRATE-0.9 % NACL/PF - Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  7. GCN #073444: OMBITASVIR/PARITAPREV/RITONAV - Ingredient Duplication (ID)
  8. GCN #074629: CLINDAMYCIN PHOSPHATE - High Dose (HD), Low Dose (LD)
  9. GCNs #074316, #074318, #074675, #074676: EMPAGLIFLOZIN/METFORMIN HCL - Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
  10. GCN #064934: ASPIRIN - Drug-Pregnancy (PG)
  11. GCNs #074851, #074853, and #076001: MORPHINE SULFATE - Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  12. GCNs #074887, #074888, and #074889: ARIPIPRAZOLE - Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
  13. GCN #063478: FLUCONAZOLE IN NACL,ISO-OSM - High Dose (HD), Low Dose (LD)
  14. GCN #075065: PSEUDOEPH/DM/ GUAIFEN/ACETAMIN - Ingredient Duplication (ID), High Dose (HD)
  15. GCN #075115: NAPROXEN CAPSAICIN/MENTHOL - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
  16. GCN #075117: ELVITEG/COBI/ EMTRIC/TENOFO ALA - Ingredient Duplication (ID)
17. GCN #075135: NAPROXEN SODIUM/MENTHOL - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
18. GCNs #075207 and #075208: MELOXICAM, SUBMICRONIZED - Drug-Pregnancy (PG)
19. GCNs #075237: DICLOFENAC SODIUM, MICRONIZED - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
20. GCNs # 074867 and # 074870: SOMATROPIN – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
21. GCN #075439: DICLOFENAC/BENZALKONIUM CHLOR – Drug Allergy (DA), Drug Pregnancy (PG), Drug Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
22. GCNs #074807, #074808, #075566: CARIPRAZINE HYDROCHLORIDE – Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
23. GCNs #075526: BUTALBITAL/ACETAMINOPHEN – Ingredient Duplication (ID), High Dose (HD)
24. GCNs #074807, #074809, #074810, and #075566: CARIPRAZINE HYDROCHLORIDE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)
25. GCN #075581: TESTOSTERONE MICRONIZED – Drug Pregnancy (PG), Additive Toxicity (AT), High Dose (HD), Low Dose (LD)
26. GCNs #075634 and #075812: EMTRICITAB/RILPIVIRI/TENOFA ALA – Ingredient Duplication (ID)
27. GCNs #075636 and #075637: METOPROLOL TARTRATE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), High Dose (HD), Low Dose (LD)
28. GCNs #075703 and #075729: GABAPENTIN/LIDOCAINE/MENTHOL – Drug-Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
29. GCNs #068868, #068870, #076198, and #076200: MORPHINE SULFATE/0.9% NAACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
30. GCN #071205: ACETAMINOPHEN – Ingredient Duplication (ID), High Dose (HD)
31. GCNs #075849 and #075850: METHOTREXATE/PF – Drug-Pregnancy (PG)
32. GCN #075823: NAPROXEN/CAPSI/MENTHOL/ME-SAL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
33. GCN #075811: DICLOFEN SOD/KINESIOLOGY TAPE – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
34. GCN #075855: GABAPENTIN/CAPSI/ME-SAL/MENTH – Drug Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
35. GCN #075937: CELECOXIB/CAPSAICIN/MENTHOL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
36. GCN #075893: DIPHENHYDRAM/PE/DM/ACETAMIN/GG – Ingredient Duplication (ID), High Dose (HD)
37. GCNs #076031, #076032, #076033, and #076035: OXYCODONE HCL – Drug Allergy (DA), Drug Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
38. GCN #076023: ACETAMINOPHEN/ D-BROMPHENIRAMIN – Ingredient Duplication (ID), High Dose (HD)
39. GCN #075937: CELECOXIB/LIDOCAINE/MENTHOL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
40. GCN #076025: PIMAVANSERIN TARTRATE – Drug Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)
41. GCNs #076097, #076101, and #076102: EMTRICITABINE/TENOFOVIR – Ingredient Duplication (ID)
42. GCN #076131: DICLOFENAC/ME-SALIC/MENTH/CAMP – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
43. GCN #076079: DOXYCYCLINE MONOHYDRATE – Drug-Pregnancy (PG)
44. GCN #076221: FENTANYL CITRATE – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
45. GCNs #076226 and #076227: DOLUTEGRAVIR SODIUM – Ingredient Duplication (ID)
46. GCNs #076256 and #076257: LINAGLIPTIN/METFORMIN HCL – Drug Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
47. GCN #076152: DICLOFENAC SODIUM – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)

**Retrospective DUR Criteria Presented**

- Buprenorphine: Buprenorphine, both by itself and in combination with naloxone, has emerged as a potential first-line treatment for opioid dependence. Buprenorphine has a reduced risk of overdose relative to full agonist therapies, and in combination with naloxone, has reduced abuse liability. A total of 4,898 continuously-eligible Medi-Cal fee-for-service beneficiaries had at least one paid claim for either buprenorphine or buprenorphine/naloxone between September 1, 2014, and August 31, 2015, with the majority of beneficiaries (80%) having ≤ 12 paid claims during the year for either buprenorphine or buprenorphine/naloxone. A review of selected
medications found very few beneficiaries with paid claims for drugs contraindicated for use with buprenorphine or buprenorphine/naloxone. The Board recommended a DUR bulletin to educate providers on the appropriate prescribing of buprenorphine. The proposed bulletin will:

- Provide an overview of the pharmacological properties of buprenorphine, along with safety considerations (especially drug interactions).
- Highlight screening guidelines and specific tools for the initial assessment of patients for initiating treatment with buprenorphine and guidelines for initiating and maintaining treatment with buprenorphine.
- Briefly describe policies and procedures relevant to opioid addiction treatment under the DATA 2000 paradigm and a summary of Medi-Cal policy efforts to expand access to buprenorphine.
- Analyze pharmacy and medical claims data for Medi-Cal fee-for-service beneficiaries currently taking buprenorphine, including an evaluation of use of additional drugs that may increase the risk of overdose and other adverse drug events, such as cytochrome-P450 inducers and inhibitors.

- Nicotine replacement therapy (NRT): A statewide evaluation conducted by the California Diabetes Program estimated that the smoking prevalence among adult Medi-Cal beneficiaries in 2009 was 20% (vs. 14% statewide). Smoking prevalence within California also varies by gender and county. As of July 1, 2014, two formulations of nicotine replacement therapy, nicotine polacrilex gum and lozenge, were added to the Medi-Cal List of Contract Drugs and an approved Treatment Authorization Request (TAR) is no longer needed for these drugs or for combination nicotine replacement therapy, and pharmacies no longer need to obtain or verify a letter or certificate prior to dispensing. All paid claims for smoking cessation drugs with dates of service between August 1, 2014, and July 31, 2015, were reviewed for Medi-Cal fee-for-service beneficiaries. As shown in Table 3, there was an increase in utilizing beneficiaries for nicotine polacrilex gum (went from 85 utilizing beneficiaries to 182 utilizing beneficiaries, an increase of 114%) and nicotine polacrilex lozenge (went from 31 utilizing beneficiaries to 44 utilizing beneficiaries, an increase of 42%). Before the addition of the gum and lozenge NRT formulations to the Medi-Cal List of Contract Drugs, the use of NRT combination therapy (that is, use of patch daily plus either gum or lozenge as needed for cravings) was very low among the Medi-Cal fee-for-service population, with only 33 beneficiaries having paid claims for both the patch and another form of NRT (between August 1, 2013, and June 30, 2014). However, the number of beneficiaries initiating NRT combination therapy had increased from four beneficiaries to 16 beneficiaries in the month following the addition of the gum and lozenge NRT formulations to the Medi-Cal List of Contract Drugs, suggesting the removal of the TAR requirement could be helpful in expansion of NRT combination therapy. A review of the claims data in the year following this policy change shows that 86 beneficiaries initiated NRT combination therapy between August 1, 2014, and July 31, 2015. The Board recommends educational outreach to Consider DUR educational outreach letters to pharmacies and providers that service Medi-Cal beneficiaries in the counties with the highest smoking rates in California. Letters would include information about
recent legislation in California to promote use of NRT and the benefits of NRT combination therapy.

- **Skeletal muscle relaxants:** As of January 11, 2012, carisoprodol was added to the Controlled Substances Act as a schedule IV controlled substance and is currently only available to Medi-Cal fee-for-service beneficiaries with an approved *Treatment Authorization Request* (TAR). The DUR Board expressed an interest in finding out more information about the utilization of carisoprodol and other skeletal muscle relaxants in the Medi-Cal fee-for-service population. All paid claims for skeletal muscle relaxants in the Medi-Cal fee-for-service program between September 1, 2014, and August 31, 2015, were evaluated. A total of 25,797 Medi-Cal fee-for-service beneficiaries had at least one paid claim for a skeletal muscle relaxant between September 1, 2014, and August 31, 2015, with the majority of beneficiaries (n=24,258; 94%) having at least one paid claim during the year for baclofen. A review of the 703 beneficiaries with at least one paid claim for carisoprodol found the majority of these beneficiaries (n=647; 92%) also had at least one paid claim for an opioid and/or a benzodiazepine during the measurement year, with a total of 256 beneficiaries (36%) having at least one paid claim for both opioids and benzodiazepines. A review of demographic characteristics for the carisoprodol study population shows those beneficiaries with a paid claim for any opioid and any benzodiazepine were predominantly female, between 18 and 39 years of age, and white/Caucasian, non-Hispanic. Finally, the distribution of beneficiaries by California region of residence showed the fewest beneficiaries in the study population reside in the Bay Area and Los Angeles regions, while the more rural North and Mountain region had the greatest number of beneficiaries in the study population. The Board recommends both educational outreach to prescribers for patients in the carisoprodol study population who have paid claims for opioids and benzodiazepines and a DUR educational bulletin to promote the appropriate prescribing of skeletal muscle relaxants. The proposed bulletin will:
  - Provide an overview of the safety considerations when prescribing skeletal muscle relaxants (especially drug interactions)
  - Describe the triple threat (the simultaneous use of opioids, benzodiazepines, and skeletal muscle relaxants) and highlight the potential lethal consequences of concomitant use of these three drugs

- **PCSK9 Inhibitors:** Recent editorials argue that PCSK9 inhibitors are priced so high they aren't worth it, except for a tiny fraction of high-risk patients who are statin-intolerant. According to the expert consensus statement published online April 1, 2016, in the Journal of the American College of Cardiology, the American College of Cardiology (ACC) updated their recommendations for the management of elevated LDL cholesterol levels in high-risk patients, specifically addressing the use of non-statin therapies, such as PCSK9 inhibitors and ezetimibe in patients unable to achieve sufficient LDL-cholesterol lowering. The updated guidelines recommend that high-risk patients who require additional LDL-cholesterol lowering beyond that achieved with a statin, the first second-line agent should be ezetimibe 10 mg daily and only after ezetimibe has been tried should physicians consider adding or

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replacing ezetimibe with one of the PSCK9 inhibitors. Paid claims for PCSk9 inhibitors with dates of service between August 27, 2015 (FDA-approval date) and March 31, 2016 were reviewed for Medi-Cal fee-for-service beneficiaries. During this time period, less than 10 beneficiaries were identified as having a paid claim for evolocumab, for a total number of 17 paid claims. There were no paid claims for alirocumab identified during this time period. Of note, all beneficiaries had at least one prior paid claim for ezetimibe before evolocumab. Given the low utilization of these drugs in the Medi-Cal fee-for-service population and evidence that prescribing of these drugs follows updated clinical guidelines, the Board had no recommendations for further action regarding PCSK9 inhibitors.

• Methadone: 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. As DHCS had discussed following the suggestion from CMS to require an approved Treatment Authorization Request (TAR) for methadone, a retrospective review was conducted in order to determine the current utilization of methadone. For this review all Medi-Cal fee-for-service paid claims for methadone with dates of service between July 1, 2015, and December 31, 2015, were included. 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 10 mg 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 from opioid overdose. Concomitant paid claims for naloxone were also requested, as was data regarding use of other opioids. Subsequent to this DUR Board meeting, DHCS suspended methadone from the Medi-Cal List of Contract Drugs effective July 1, 2016, so plans for further evaluation were halted at that time.

• HIV Antiretroviral Medications: On January 1, 2014, California expanded the eligibility for Medi-Cal 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 antiretroviral medication used to treat or prevent human
immunodeficiency virus (HIV) infection. 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. 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, with a more rapid increase seen in the use of medications newly approved by the FDA. 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 were compared, stratified by whether the beneficiary was enrolled in Medi-Cal FFS or a Medi-Cal managed care plan as of December 2014. 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 and they were more likely to be younger and live in Los Angeles County. Due to limitations involving access to medical claims data from Medi-Cal managed care beneficiaries, the Board did not request any further evaluation of these data or propose any educational interventions on this topic.

**Provider-specific Interventions**

**Educational articles and alerts:**
- Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects – April 2016
- Alert: California Upgrades Prescription Drug Monitoring Program to CURES 2.0 – January 2016
- Clinical Review: Concomitant Use of Anticholinergics and Antipsychotics – November 2015
- 2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus – September 2016

**Provider intervention letters:**
- Morphine Equivalent Daily Dose – March 2016 and July 2016
- Anticholinergics – August 2015
Ongoing DUR Board Projects

The DUR Board goals for FFY 2016 were as follows:

- Conduct systematic review to identify therapeutic drug categories and establish relative cost comparisons that also comply with contractual requirements for cost confidentiality
- Promote dialogue, collaboration, and recommend best practices in pharmacy utilization management on drugs that are commonly used in both Medi-Cal fee-for-service and managed care
- Recommend prospective DUR alerts system design as part of new CAMMIS system
- Conduct studies to evaluate various methods in the design of “dear doctor” letters
- Collaborate with other agencies in the use of Morphine Equivalent Daily Dose (MEDD) to prevent opioid overdose
- Establish DUR 5-year trending reports on selected measures
- Collaborate with other agencies in improving psychotropic medication use for all populations
- Establish a learning collaborative with managed care health plans and other agencies to promote best practices using academic detailing
- Align DUR board goals with DHCS Quality Strategy

The following are ongoing DUR Board projects:

- 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 opioids, MEEDD, and prescription drug abuse.
- Academic Detailing – Educational intervention is key to improving drug utilization, and these interventions may improve prescribing patterns. In recent years, the Drug Use Review (DUR) Board has spearheaded many initiatives to disseminate information to providers in an effort to improve prescribing. In addition to publishing educational bulletins, the DUR Board initiated several controlled studies aimed at identifying the most effective way to deliver messages, including writing letters and obtaining written feedback from prescribers. During FFY 2016, the DUR Board set an ambitious goal to establish a learning collaborative with managed care plans (MCPs) and other agencies to promote best practices using academic detailing. The first academic detailing conference is to be held in FFY 2017 on October 20, 2016.
- A report entitled, “Comprehensive Medication Management Programs: Description, Impacts and Status in Southern California, 2015” was published on 12/23/2015. Ms. Chan commended the California Department of Public Health for making this report available and congratulated Board member Dr. Marilyn Stebbins for her contribution to this important report.
**DUR Board Members**

The following members served on the DUR Board, either in part or for the entire duration, of FFY 2016:

<table>
<thead>
<tr>
<th>Member</th>
<th>Specialty/Affiliation</th>
</tr>
</thead>
</table>
| Andrew L. Wong, M.D. Chair    | Chair 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:


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.

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 2016 are shown in Table 1.

Table 1. Prospective DUR Cost-Savings for Federal Fiscal Year (FFY) 2016.

<table>
<thead>
<tr>
<th>Prospective DUR alert</th>
<th>Total claims cancelled or not overridden</th>
<th>Average reimbursement dollars paid to pharmacies per claim</th>
<th>Multiplier</th>
<th>Total estimated costs avoided through prospective DUR</th>
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<tbody>
<tr>
<td>Over Utilization (Early Refill)</td>
<td>695,449</td>
<td>$373</td>
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<td>Therapeutic Duplication</td>
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<td>Ingredient Duplication</td>
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<td>Under Utilization (Late Refill)</td>
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<td>High Dose</td>
<td>89,179</td>
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<td>Low Dose</td>
<td>40,269</td>
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<td>Clinical Misuse (Additive Toxicity)</td>
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<tr>
<td>Drug-Drug Interaction</td>
<td>12,400</td>
<td>$544</td>
<td>0.8</td>
<td>$5,396,480</td>
</tr>
<tr>
<td>Drug-Disease Contraindication</td>
<td>4,935</td>
<td>$396</td>
<td>0.8</td>
<td>$1,563,408</td>
</tr>
<tr>
<td>Drug Allergy</td>
<td>412</td>
<td>$85</td>
<td>0.8</td>
<td>$28,016</td>
</tr>
<tr>
<td>Drug Age</td>
<td>144</td>
<td>$256</td>
<td>0.8</td>
<td>$29,491</td>
</tr>
<tr>
<td><strong>TOTAL: All Alerts</strong></td>
<td><strong>1,460,934</strong></td>
<td><strong>$348</strong></td>
<td><strong>20.0%</strong></td>
<td><strong>$229,440,897</strong></td>
</tr>
</tbody>
</table>

1Multiple alerts can be generated per claim, so there may be duplicate alerts cancelled or overridden.
2Average 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 2016.
3The 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 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 and optimal prescribing standards to engage prescribers to use minimum number of psychotropic medications, at the lowest appropriate dosage and at the appropriate age.

In FFY 2016, the state of California was selected to join the CMS Antipsychotic Drug Use in Children (ADC) Affinity Group, through a collaborative effort between DUR Board and other state agencies including the Department of Health Care Services. The goal of the ADC Affinity Group was to focus on strategies to improve the quality of care for children who are prescribed antipsychotic drugs. The group also identified and encouraged strategies aimed at reporting on the 2016 Child Core Set measure for Medi-Cal/CHIP: Use of Multiple Concurrent Antipsychotics in Children and Adolescents. CMS supported California’s efforts to improve quality of care by providing learning opportunities regular meetings and communications between states. Monthly 1:1 calls with CMS began in March 2016 and continued throughout FFY 2016. In addition, quarterly group calls were held with other states and QI experts. Activities of the ADC Affinity Group were shared with the DUR Board at each meeting and input from the Board was welcomed. With the support of CMS and the DUR Board, the DUR program finalized a proposal in late FFY 2016 to repeat the successful DUR educational outreach intervention focused on metabolic monitoring efforts among children and adolescent taking antipsychotic medications.

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 providers who prescribed greater than a 120 mg morphine equivalent daily dose (MEDD) of prescription opioids. The proposal aimed to improve the quality of pain treatment among non-cancer, non-hospice Medi-Cal fee-for-service beneficiaries at increased risk of opioid overdose. A total of 132 prescribers were selected for the
mailing, representing 155 beneficiaries. The mailing included information about how to calculate MEDD, the increased risk of overdose at higher MEDD, and information about the concomitant prescribing of naloxone for high-risk patients.

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)

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 FFY 2016, CDSS and DHCS continued to share key data regarding psychotropic medication use among children and youth in foster care through a website accessible to the public.

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 as part of the Foster Care QI Project
   c. Development of clinical performance measures for the state on psychotropic medication use in children
   d. Promotion of the use of buprenorphine to treat opioid dependence, encouraging providers to obtain a waiver to prescribe buprenorphine per DATA 2000 guidelines
   e. DUR board member serves on Quality Improvement Project Expert Panel
   f. DUR board member has applied to serve on the Opioid Workgroup
g. Presentation of DUR educational bulletin findings at DHCS Learning Series

5. **Academic Detailing** – In recent years, the DUR Board has spearheaded many initiatives to disseminate information to providers in an effort to improve prescribing. In addition to publishing educational bulletins, the DUR Board initiated several controlled studies aimed at identifying the most effective way to deliver messages, including writing letters and obtaining written feedback from prescribers. During FFY 2016, the DUR Board set an ambitious goal to establish a learning collaborative with managed care plans and other agencies to promote best practices using academic detailing. The first academic detailing conference is to be held in FFY 2017 on October 20, 2016 at DHCS in Sacramento. Clinical topics will include opioids use and misuse, naloxone for opioids overdose, and diabetes, and program topics will include examples of best practices, team-based care, and developing a business case for academic detailing.
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) 2016, 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 2016, 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 2016 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 2016, the DUR Board reviewed prospective DUR criteria for 44 drugs and comprehensively reviewed the status of all drugs for two prospective alerts: drug-pregnancy (PG) and late refill (LR). In addition, retrospective DUR criteria for two drugs and four drug therapeutic categories were reviewed. Finally, seven 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 two 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, Conduent (formerly known as Xerox State Healthcare, LLC), and the University of California, San Francisco.
<table>
<thead>
<tr>
<th>Top 10 PA Requests by Drug Name</th>
<th>Top 10 PA Requests by Drug Class</th>
<th>Top 5 Claim Denial Reasons (i.e. QL, Early Refill, PA, Duplication)</th>
<th>% of Total Spent for Drugs by Amount Paid</th>
<th>Top 10 Drug Names by Claim Count</th>
<th>Drugs By Claim Count % of Total Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARIPIPRAZOLE</td>
<td>SECOND GENERATION ANTI-PSYCHOTICS</td>
<td>Claim requires an approved Treatment Authorization Request (TAR) due to beneficiary age</td>
<td>ARIPIPRAZOLE</td>
<td>12.3%</td>
<td>QUETIAPINE FUMARATE</td>
</tr>
<tr>
<td>RISPERIDONE</td>
<td>OPIOID ANALGESICS AND COMBINATIONS</td>
<td>Claim requires an approved TAR due to exceeding quantity limits, days supply, and/or frequency</td>
<td>QUETIAPINE FUMARATE</td>
<td>5.5%</td>
<td>IBUPROFEN</td>
</tr>
<tr>
<td>PALIPERIDONE PALMITATE</td>
<td>CNS STIMULANTS</td>
<td>Claim requires an approved TAR because claim exceeds the 6 prescription limit</td>
<td>LURASIDONE HCL</td>
<td>4.1%</td>
<td>ARIPIPRAZOLE</td>
</tr>
<tr>
<td>QUETIAPINE FUMARATE</td>
<td>ANTI-CONVULSANTS</td>
<td>Claim requires an approved TAR because beneficiary does not have the appropriate documented diagnosis on file for this drug</td>
<td>OLANZAPINE</td>
<td>3.9%</td>
<td>RISPERIDONE</td>
</tr>
<tr>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>ANTI-DEPRESSANTS</td>
<td>Duplicate claim</td>
<td>EMTRICITABINE/TENOFOVIR (TDF)</td>
<td>3.4%</td>
<td>ASPIRIN</td>
</tr>
<tr>
<td>HALOPERIDOL</td>
<td>BENZO-DIAZEPINES</td>
<td>XXXXXXX</td>
<td>PALIPERIDONE PALMITATE</td>
<td>3.1%</td>
<td>OLANZAPINE</td>
</tr>
<tr>
<td>METHYL-PHENIDATE HCL</td>
<td>FIRST GENERATION ANTI-PSYCHOTICS</td>
<td>XXXXXXX</td>
<td>ABACAVIR/DOL UTEGRAVIR/LA MIVUDI</td>
<td>2.3%</td>
<td>BENZTROPINE MESYLATE</td>
</tr>
<tr>
<td>LORAZEPAM</td>
<td>INSULIN</td>
<td>XXXXXXX</td>
<td>ELVITEG/CABI/ EMTRIC/ TENOFO DIS</td>
<td>2.1%</td>
<td>DOCUSATE SODIUM</td>
</tr>
<tr>
<td>BUPRENORPHINE</td>
<td>PROTON PUMP INHIBITORS</td>
<td>XXXXXXX</td>
<td>EFAVIRENZ/ EMTRICITAB/ TENOFO DIS</td>
<td>2.0%</td>
<td>ALBUTEROL SULFATE</td>
</tr>
<tr>
<td>ZIPRASIDONE</td>
<td>BRONCHO-DILATORS</td>
<td>XXXXXXX</td>
<td>EMTRICITA/ RILPIVIRINE/ TENOF DF</td>
<td>1.3%</td>
<td>LORATADINE</td>
</tr>
</tbody>
</table>

Table 1 - 50
# TABLE 2 - GENERIC UTILIZATION DATA

<table>
<thead>
<tr>
<th></th>
<th>Single-Source (S) Drugs</th>
<th>Non-Innovator (N) Drugs</th>
<th>Innovator Multi-Source (I) Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Number of Claims</strong></td>
<td>1,997,802</td>
<td>8,479,011</td>
<td>1,661,427</td>
</tr>
<tr>
<td><strong>Total Reimbursement Amount Less Co-Pay</strong></td>
<td>$2,336,885,404</td>
<td>$327,116,716</td>
<td>$886,674,253</td>
</tr>
</tbody>
</table>

**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.
DUR educational articles are published in provider bulletins and posted on the DUR webpage. This biennial evaluation report provides detailed evaluations of the following DUR educational articles, which were published between October 2012 and September 2014:

- YOU Can Influence Influenza Rates! Recommend Vaccination for Everyone 6 Months of Age and Older – November 2012
- Prevent Pertussis: Improve the Adult Tdap Vaccination Rate – November 2012
- Over-the-Counter Eye Drops and Nasal Sprays: Drug Safety Communication – November 2012
- Improving the Quality of Care: Updated Guidelines for Migraine Prevention – February 2013
- Alert: April 27, 2013 is National Prescription Drug Take-Back Day – March 2013
- Improving the Quality of Care: Therapeutic Monitoring in Diabetes – April 2013
- Improving the Quality of Care: Therapeutic Monitoring of Anticonvulsants – August 2013
- Immunization Update: Tdap Vaccination with Every Pregnancy – November 2013
- Improving the Quality of Care: Medication Management in Asthma – December 2013
- Clinical Review: Diagnosis and Treatment of Cough in Children and Adults – March 2014
- Improving the Quality of Care: Appropriate Monitoring of Medication Therapy – May 2014
- In the News: Prescription Drug Abuse and Diversion of Controlled Substances – August 2014
- 2014 Immunization Updates: Influenza, Tdap and HPV – September 2014
The evaluation effort reviewed each educational article in a systematic way, using the following format:

- Background
- Purpose
- Data Criteria and Findings
- Analysis
- Limitations
- Research/Policy Recommendations
- Clinical Recommendations

Many factors may influence the prescribing and dispensing practices of Medi-Cal providers, making it difficult to accurately measure the full impact of the educational articles. Such factors may include, but are not limited to, the following:

- Changes and updates to treatment guidelines and recommendations
- Beneficiary expectations and requests and healthcare habits and behavior
- Direct-to-consumer advertising
- Provider training and experience
- Anecdotal experience
- Provider resistance

The purpose of DUR educational articles is to apprise Medi-Cal providers of current treatment guidelines and recommendations on drugs, disease states, and medical conditions. These articles contain valuable information that is effective when used as a part of an overall campaign to disseminate important information to providers. The following recommendations may help to improve accessibility, reach, and interest of educational articles to the Medi-Cal provider community:

- Continue to distribute articles with provider bulletins but keep articles separate and independent from the bulletin in order to increase visibility.
- Distribute article links to medical and pharmaceutical organizations/associations for distribution to their members or publications in journals and/or bulletins.
- Encourage prescribers and pharmacists to sign up for distribution of articles via the Medi-Cal Subscription Service (MCSS).
- Facilitate continuing medical education (CME) and/or continuing education (CE) opportunities to prescribers and pharmacists related to article content
- Incorporate case studies into articles.
- Package articles with other collateral materials for distribution through various media channels such as posters, postcard mailings and flyers that highlight the recommendations of each the article.
• Prepare shorter educational articles that are published more frequently that bullet or highlight important points.
• When appropriate, disseminate lay version to beneficiaries to promote physician uptake and set beneficiary expectations.
• Continue to support the direct link between articles and retrospective DUR educational outreach to prescribers and pharmacists.
• Include patient-specific profiles for educational outreach where the primary objective is an improvement in the quality of care.
• Use provider-specific profiles for educational outreach where the primary objective is an improvement in the quality of prescribing or dispensing.
Biennial Review: Evaluation of Educational Articles

1. YOU Can Influence Influenza Rates! Recommend Vaccination for Everyone 6 Months of Age and Older – November 2012

- **Background:** Since 2010, the Advisory Committee on Immunization Practices (ACIP) has recommended annual influenza vaccination for all persons 6 months of age or older. Despite evidence that the influenza vaccine is cost effective and may prevent influenza-related hospitalization and death, influenza vaccination rates are approximately half the rate of national goals as a part of Healthy People 2020. For the 2011-12 influenza season, the cumulative influenza vaccination coverage estimate in California was 40.5% for all persons 6 months of age and older, just under the national average of 41.8%. A review of pharmacy and medical claims data found that during the 2011-12 influenza season over half (54.1%) of Medi-Cal fee-for-service beneficiaries received their shots at a pharmacy. Among all age groups under 65 years of age, more beneficiaries had a paid claim for the influenza vaccine through their pharmacy than at their physician’s office.

- **Purpose:** The purpose of this biennial review is to review updates to the ACIP recommendations for influenza vaccine since the article was published and to revise the facts provided about influenza in the article. In addition, data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the percentage of Medi-Cal fee-for-service beneficiaries that received their influenza vaccine at a pharmacy during the 2015-2016 influenza season.

- **Data Criteria and Findings:** The biennial review followed the same criteria as the published article. All paid pharmacy and medical claims for influenza vaccination with dates of service between July 1, 2015, and June 30, 2016, were reviewed, with no beneficiaries excluded from the analysis.

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 01/01/09 – 06/30/12</th>
<th>Biennial review data: 07/01/15 – 06/30/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage receiving influenza vaccine at a pharmacy</td>
<td>54.1%</td>
<td>60.2%</td>
<td>6.1%</td>
</tr>
</tbody>
</table>

This biennial review also researched if there were any updates to ACIP recommendations on influenza vaccination since the original article, which was published in November 2012. For 2016-17 the ACIP recommendations for
influenza vaccination of persons with egg allergy were modified. People with egg allergies can now receive any licensed, recommended age-appropriate influenza vaccine and no longer have to be monitored for 30 minutes after receiving the vaccine. People with severe egg allergies should be vaccinated in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic conditions. Also for the 2016-17 influenza season, in light of low effectiveness in the United States during the 2013–14 and 2015–16 seasons, ACIP made the recommendation that live, attenuated influenza vaccine (LAIV) should not be used. CDC only recommends use of the flu shot (inactivated influenza vaccine or IIV) and the recombinant influenza vaccine (RIV) during 2016-17.

Updates to influenza facts provided in the original DUR article:

- For the 2015-16 influenza season, the cumulative influenza vaccination coverage estimate in California was 43.7% for all persons 6 months of age and older (up from 40.5% in 2011-12), which still remains below the national average of 45.6% (up from 41.8% in 2011-12).
- On December 9, 2016, the Centers for Disease Control and Prevention (CDC) posted estimates of seasonal flu deaths in the United States from 2010-11 to 2013-14, which ranged from a low of 12,000 (during 2011-12) to a high of 56,000 (during 2012-13). These estimates from recent years are higher than the previous range given of 3,000 to 49,000 deaths per year, which looked at data from 1976-77 to 2006-07.
- In 2014, influenza and pneumonia ranked as the 8th most common cause of death in the United States, up from 9th in 2010.
- During the 2015-16 influenza season, the California Department of Public Health (CDPH) received 144 reports of influenza-related deaths among persons less than 65 years of age, compared with 51 deaths in 2011-12.

- **Analysis:** This biennial review shows that Medi-Cal beneficiaries are now more likely to receive their influenza vaccination at a pharmacy than they were during the 2011-12 influenza season. In the original DUR article the percentage of beneficiaries receiving their vaccine at the pharmacy was 54.1%, and this increased in the biennial review to 60.2%. These findings show the increased importance that all health care providers, including pharmacy technicians and other pharmacy staff, feel comfortable addressing myths about influenza and the influenza vaccine. The updated data show that influenza continues to be a leading cause of preventable death in the United States and efforts to increase the rate of influenza vaccination should continue to be a public health priority.
• **Limitations:** These data do not include any pharmacy or medical claims that were not processed as claims through the Medi-Cal program.

• **Research/Policy Recommendations:**
  1. Continue to educate patients and providers about the importance of annual influenza vaccination for anyone 6 months of age and older.
  2. Work with CDPH to promote that all ACIP-recommended adult immunizations are now available as a Medi-Cal pharmacy benefit.

• **Clinical Recommendations:**
  1. All prescribers and pharmacies should review immunization status and other evidence of immunity to vaccine-preventable diseases for all patients.
  2. All health care providers should routinely encourage flu vaccine for all patients 6 months of age and older.
  3. All health care providers should feel comfortable addressing myths about influenza and the influenza vaccine.
2. Prevent Pertussis: Improve the Adult Tdap Vaccination Rate – November 2012

- **Background:** Pertussis, also known as whooping cough, is caused by the bacterium *Bordetella pertussis* and is a highly contagious respiratory disease that is spread from person to person through respiratory secretions or close contact with an infected individual. Once a person has become infected, they may easily spread the disease to those around them, putting at risk infants who have not been vaccinated and the elderly who are more likely to experience serious complications. Driven by the epidemiological trend of increasing pertussis incidence across multiple age ranges, ACIP expanded its recommendations to include all seniors, and not just those who plan to be in contact with infants. Currently, there are two approved tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) formulations available for adolescents and adults: Boostrix® and Adacel®. Boostrix® should be used for adults aged 65 years and older when available and feasible, however, ACIP concluded that either Boostrix® or Adacel® administered to a person 65 years or older is immunogenic and would provide protection. A review of pharmacy and medical claims data found that between January 1, 2009, and June 30, 2012, almost all Medi-Cal fee-for-service beneficiaries received their Tdap vaccination from their physician. Only 1.6% of beneficiaries received the Tdap vaccination in a pharmacy, in comparison to 54.1% of beneficiaries who were vaccinated for influenza at a pharmacy during that same time period.

- **Purpose:** The purpose of this biennial review is to determine if there have been any updates to the ACIP recommendations for pertussis vaccine in adults since the original DUR educational article was published in November 2012. In addition, data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the percentage of Medi-Cal fee-for-service beneficiaries that received their Tdap vaccine at a pharmacy.

- **Data Criteria and Findings:** All paid pharmacy and medical claims for Tdap vaccination with dates of service between July 1, 2015, and June 30, 2016, were reviewed, with no beneficiaries excluded from the analysis.

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 01/01/09 – 06/30/12</th>
<th>Biennial review data: 07/01/15 – 06/30/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage receiving Tdap vaccine at a pharmacy</td>
<td>1.6%</td>
<td>6.1%</td>
<td>4.5%</td>
</tr>
</tbody>
</table>
This biennial review evaluates the same ACIP recommendations as the original article, which was written during in November 2012.

1. October 24, 2012: ACIP votes to update their recommendations for the use of Tdap among all pregnant women and these recommendations are published in the February 22, 2013, edition of the Morbidity and Mortality Weekly Report (MMWR). Tdap is now recommended during each pregnancy, optimally between 27 and 36 weeks gestation, as B. pertussis antibodies can be transferred from vaccinated mothers to their infants and may help protect them until they are old enough to be vaccinated at six weeks of age or older. If Tdap is not administered during pregnancy, it should be administered immediately postpartum. However, protection is optimal when newborns have antibodies transferred in utero from prenatal vaccination.

2. In October 2014, ACIP considered Tdap revaccination of healthcare personnel. After review of available data, ACIP maintains the current recommendation for healthcare personnel to receive a single dose of Tdap and at this time does not recommend routine administration of additional doses.

**Analysis:** This biennial review shows that Medi-Cal beneficiaries are now more likely to receive their Tdap vaccination at a pharmacy than they were during the 2009-12 analysis in the original DUR article. In the original DUR article the percentage of beneficiaries receiving their vaccine at the pharmacy was only 1.6%, and this increased in the biennial review to 6.1%. The biennial review of the Tdap guidelines shows expanding guidelines that aim to protect populations vulnerable to B. pertussis infection. As of January 23, 2017, CDPH reported 1,540 pertussis cases with onset in 2016 in California for a preliminary state rate of 3.9 cases per 100,000 population during 2016. However, in 2016 there were two deaths reported due to pertussis in infants younger than 3 months of age at the time of disease onset.

**Limitations:** These data do not include any pharmacy or medical claims that were not processed as claims through the Medi-Cal program.

**Research/Policy Recommendations:**

1. Continue to educate patients and providers about pertussis, in particular among pregnant women and anyone who anticipates having close contact with an infant aged < 12 months.

2. Work with CDPH to promote that all ACIP-recommended adult immunizations are now available as a Medi-Cal pharmacy benefit.
• **Clinical Recommendations:**
  1. All prescribers and pharmacies should review immunization status and other evidence of immunity to vaccine-preventable diseases for all patients.
  2. Routinize the offer of prenatal Tdap for all pregnant women at the beginning of the third trimester to protect babies who might be born prematurely. Consider combining Tdap vaccination with the glucose screening test at 28 weeks and/or calling your electronic health record (EHR) vendor to request a flag that automatically reminds you to offer the vaccination to all prenatal patients.
  3. Given the high rate of pharmacy-administered influenza vaccinations, pharmacies should offer Tdap boosters to all eligible adults at the same time as the influenza vaccine.
  4. All health care providers should participate in the California Immunization Registry (CAIR), a computerized information system that collects immunization data from public and private health care providers and combines it into one complete record for individuals in California.
  5. Visit the CDPH website to stay informed on pertussis outbreaks.

- **Background:** On October 25, 2012, the U.S. Food and Drug Administration (FDA) issued a warning that accidental ingestion (swallowing) by children of over-the-counter (OTC) eye drops used to relieve redness and nasal decongestant sprays can result in serious harm. Between 1985 and 2012, the FDA identified 96 cases in which children ranging from 1 month to 5 years accidentally swallowed products containing these ingredients. While no deaths were reported, more than half of the cases (53) reported hospitalization because of symptoms that included nausea, vomiting, lethargy, tachycardia, and coma. The eye drops and nasal sprays involved in the cases of accidental ingestion contained the active ingredients tetrahydrozoline, oxymetazoline, or naphazoline.

- **Purpose:** The purpose of this biennial review is to review if there were any warnings or actions by the FDA regarding adverse effects from OTC eye drops and nasal sprays since the original DUR alert was published in November 2012.

- **Data Criteria and Findings:** There were no additional FDA communications on this topic since the original drug safety communication on October 25, 2012. In January of 2012, the U.S. Consumer Product Safety Commission (CPSC) proposed a rule to require child-resistant packaging for all products containing at least 0.08 mg of an imidazoline derivative. However, this rule has not been finalized.

- **Analysis:** Cases of accidental ingestion of OTC redness-relief eye drops or nasal decongestant sprays containing the active ingredients tetrahydrozoline, oxymetazoline, or naphazoline have resulted in serious adverse events in young children 5 years of age and younger.

- **Limitations:** None.

- **Research/Policy Recommendations:** None.

- **Clinical Recommendations:**
  1. Advise parents and caregivers to call the toll-free Poison Help Line (1-800-222-1222) and to seek emergency medical care if their child accidentally swallows OTC eye drops or nasal decongestant sprays.
  2. Advise consumers to store medications, including OTC eye drops or nasal decongestant sprays out of reach of children at all times.
4. Improving the Quality of Care: Updated Guidelines for Migraine Prevention – February 2013

- **Background**: Migraine is a highly prevalent, chronic, episodic condition affecting approximately 12 percent of adults each year, with prevalence three times higher in women than men. While triptans are the recommended first-line treatment for moderate to severe migraine headaches and for mild migraine headaches resistant to treatment with nonsteroidal anti-inflammatory drugs or combination analgesics, patients should be evaluated for possible preventive treatment for migraine, given on an ongoing basis whether or not an attack is present. While no standardized measures exist for monitoring migraine quality of care, a 2012 study on migraine-related quality of care across 10 health plans attempted to establish benchmarks in migraine care and identify potential quality issues. Pharmacy-specific measures included overutilization of triptan therapy, underutilization of preventive drugs, triptan use and concurrent cardiac contraindications, and triptan use and concomitant therapy with selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs). The original DUR article found that 51.6% of Medi-Cal beneficiaries with at least one paid claim for a triptan medication during a one-year period had at least two prescriptions for a migraine preventive medication during that same time period.

- **Purpose**: The purpose of this biennial review is to review any possible updates to the clinical guidelines for migraine prevention since the article was published and to re-examine migraine quality of care among triptan users in the Medi-Cal fee-for-service population, in order to determine if there have been any changes in use and prescribing patterns over time.

- **Data Criteria and Findings**: For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
  1. Inclusion criteria:
     i. Medi-Cal fee-for-service beneficiaries with at least one paid pharmacy claim for a triptan between October 1, 2011 and September 30, 2012 (the measurement year).
     ii. Adults aged 18 to 64 years throughout the measurement year.
     iii. Continuous eligibility for the Medi-Cal FFS program throughout the measurement year.
  2. Exclusion criteria:
     i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.
<table>
<thead>
<tr>
<th><strong>Medi-Cal fee-for-service population</strong></th>
<th><strong>Article data: 10/01/11 – 09/30/12</strong></th>
<th><strong>Biennial review data: 11/01/15 – 10/31/16</strong></th>
<th><strong>Percent change</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries identified with at least one paid claim for a triptan</strong></td>
<td>5,184</td>
<td>4,803</td>
<td>-7.9%</td>
</tr>
<tr>
<td>Percentage with no coded migraine diagnosis</td>
<td>33.0%</td>
<td>52.5%</td>
<td>19.5%</td>
</tr>
<tr>
<td>Percentage with at least 2 prescriptions for a migraine preventive during the measurement year</td>
<td>51.6%</td>
<td>32.1%</td>
<td>-19.5%</td>
</tr>
<tr>
<td>Percentage with a coded diagnosis of cardiac contraindication(s) between ages 18-49 during the measurement year</td>
<td>5.9%</td>
<td>7.8%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Percentage with a coded diagnosis of cardiac contraindication(s) between ages 50-64 during the measurement year</td>
<td>10.8%</td>
<td>12.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Percentage with at least 30 tablets/capsules dispensed of an SSRI/SNRI during the measurement year</td>
<td>45.9%</td>
<td>51.2%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Percentage of high users of triptans (more than 12 tablets per month on average, during the measurement year)</td>
<td>3.1%</td>
<td>10.6%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Percentage of high users of triptans with at least 2 prescriptions for a migraine preventive during the measurement year</td>
<td>60.6%</td>
<td>64.9%</td>
<td>4.3%</td>
</tr>
</tbody>
</table>

- **Analysis:** The biennial review shows that the total number of utilizing beneficiaries in the Medi-Cal fee-for-service program with a paid claim for a triptan during a one-year time period decreased by 7.9% since the original DUR educational article, which is a lesser rate than the overall number of utilizing beneficiaries during this same time period in the fee-for-service program (decreased by 23.1%). A review of selected migraine quality-of-care benchmarks
evaluated in the original article found several areas in which performance was worse during the biennial review than in the original article. For example, among beneficiaries with a paid claim for a triptan, more than half (52.5%) did not have a coded diagnosis for migraine, up 19.5% from the original article, and only 32.1% had two or more claims for a migraine preventive medication (a 19.5% decrease since the original article). In addition, in the biennial review, a greater percentage of beneficiaries with a paid claim for a triptan had more than 12 paid claims for triptans and a greater percentage of beneficiaries had cardiac contraindications in comparison to the original article. There continue to be no established standardized quality measures for migraine, which may be contributing to the selected measures in these evaluations not showing improvement over time.

- **Limitations:** None.

- **Research/Policy Recommendations:**
  1. Continue to monitor the use of triptans in the Medi-Cal fee-for-service population.
  2. Continue to assess the need for additional educational interventions regarding migraine quality of care, especially among high users of triptans with known contraindications for triptan therapy.
  3. Continue to monitor literature and professional organizations for standardized quality measures for migraine.

- **Clinical Recommendations:**
  1. Patients who experience migraine headaches should be evaluated for therapeutic appropriateness of a preventive treatment regimen for migraine on a regular basis.
  2. The selection of a migraine preventive medication should include an evaluation of the following: 1) side-effect profile, 2) patient comorbid conditions, 3) potential medication interactions, 4) evidence-based efficacy and 5) patient preference.
  3. Understand that clinical efficacy of migraine prevention medication usually is reported in 3 to 6 weeks, but an 8 to 12 week trial is recommended to reach therapeutic doses and observe maximal patient response.
  4. High-users of triptan medications and beneficiaries prescribed triptans who have contraindications for triptan therapy should be evaluated for therapeutic appropriateness of continued use.

- **Background:** The Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day aims to provide a safe, convenient and responsible means of disposal for prescription drugs, while also educating the general public about the potential for abuse of leftover medications. At the time the original DUR article was published in March 2013, the 5th National Prescription Drug Take-Back Day had been scheduled for April 27, 2013. Collection sites were being organized into a searchable database that was going to be available to the public by April 1, 2013 via the National Take-Back Initiative (NTBI) Public Search Web page at: [https://www.deadiversion.usdoj.gov/SEARCH-NTBI/](https://www.deadiversion.usdoj.gov/SEARCH-NTBI/).

- **Purpose:** The purpose of this biennial review is to review if there have been any updates regarding National Prescription Drug Take-Back Day since the original DUR alert was published in March 2013.

- **Data Criteria and Findings:** The DEA has continued to coordinate these events and April 29, 2017, will mark the 12th National Prescription Drug Take-Back Day. At the 11th National Prescription Drug Take-Back Day, which was held on April 30, 2016, Americans turned in more unused prescription drugs than on any of the previous 10 events. According to a press release issued by the DEA, during that event the DEA and over 4,200 state, local, and tribal law enforcement partners collected 893,498 pounds of unwanted medicines—about 447 tons—at almost 5,400 sites spread through all 50 states.

- **Analysis:** NTBI addresses a crucial public safety and public health issue. According to the 2014 National Survey on Drug Use and Health, 6.5 million Americans abused controlled prescription drugs. That same study showed that a majority of abused prescription drugs are obtained from family and friends, including from the home medicine cabinet. Drug Take Back programs are the preferred method for drug disposal as they can prevent unnecessary deaths due to accidental medication exposure while also diverting medicines from entering the environment.

- **Limitations:** None.

- **Research/Policy Recommendations:**
  1. Continue to educate patients and providers about the importance of proper medication disposal.
2. Work with key stakeholders, including pharmacies and other state agencies to help promote the NTBI.

- **Clinical Recommendations:**
  1. Health care providers should discuss with their patients the importance of informing prescribers if they decide to discontinue taking any medications.
  2. Health care providers should consider asking patients about the state of their medicine cabinets on a regular basis (particularly patients who use multiple medications and/or those who use opiates).
6. Improving the Quality of Care: Therapeutic Monitoring in Diabetes – April 2013

- **Background:** Diabetes is the seventh leading cause of death in the United States and is the leading cause of kidney failure, non-traumatic lower limb amputations and new cases of blindness among American adults. Additional diabetes-related complications include heart disease, stroke, hypertension and nervous system damage. Intensive glycemic control significantly reduces microvascular complications, including retinopathy, nephropathy and neuropathy. The American Diabetes Association (ADA) Standards of Medical Care in Diabetes – 2013 gives health care providers information regarding diabetes diagnosis, general treatment and tools to evaluate quality of care provided, while also accounting for patient-specific factors that may favor individualized targets in certain patients. Comprehensive diabetes care is also one of Medicaid’s initial core set of health care quality measures, which was published in 2012. These quality measures differ from the ADA’s Standards of Medical Care and are based on the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) diabetes performance measures, including HbA1C monitoring and lipid panel, including LDL-C measurement, for most adult patients with diabetes at least once per year. The ADA notes that psychological problems may impair an individual’s ability to carry out diabetes-related self-management tasks and compromise health, so the original article also included monitoring rates stratified by the presence or absence of a comorbid mental health condition. The original article found that Medi-Cal fee-for-service HbA1C and lipid panel monitoring rates are below those found in a sample of the national Medicaid fee-for-service population, with the lowest rates of monitoring in both study populations being those beneficiaries with a co-morbid mental health condition.

- **Purpose:** The purpose of this biennial review is to review any updates to the clinical guidelines for therapeutic monitoring in diabetes since the article was published and to re-examine monitoring rates in the Medi-Cal fee-for-service population, in order to determine if there have been any changes over time.

- **Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
  1. Inclusion criteria:
     i. Continuous eligibility for the Medi-Cal FFS program between January 1, 2016 and December 31, 2016 (the measurement year).
     ii. Between 18 and 64 years of age throughout the duration of the measurement year.
iii. Two or more paid medical claims in an outpatient setting or one or more paid medical claims in an inpatient setting, with any of these ICD-9-CM codes for diabetes: 250, 357.2, 362.0, 366.41 or 648.0; and/or at least one paid claim for an anti-diabetes medication.

2. Exclusion criteria:
   i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.

Each Medi-Cal fee-for-service beneficiary meeting inclusion criteria for diabetes also was evaluated to determine whether or not they had a co-morbid mental health condition. Beneficiaries were classified as having a co-morbid mental health condition if they had a medical claim that included an ICD-9-CM code for any mental disorder; excluding organic conditions such as dementia and delirium (ICD-9-CM codes 295.00-315.99).

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 10/01/11 – 09/30/12</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries meeting the above criteria for diabetes during the measurement year with a co-morbid mental health condition</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage with at least one HbA1C screening during the measurement year</td>
<td>21.6%</td>
<td>27.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Percentage with at least one LDL screening during the measurement year</td>
<td>18.4%</td>
<td>20.6%</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Beneficiaries meeting the above criteria for diabetes during the measurement year without a co-morbid mental health condition</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage with at least one HbA1C screening during the measurement year</td>
<td>28.3%</td>
<td>36.8%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Percentage with at least one LDL screening during the measurement year</td>
<td>25.6%</td>
<td>27.9%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>
Commencing with the release of the 2015 HEDIS® performance measures, NCQA retired the LDL screening. In November 2013, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines released updated guidance for the treatment of blood cholesterol. The new recommendations removed treatment targets for LDL-C for the primary or secondary prevention of atherosclerotic cardiovascular disease (ASCVD) and recommended high- or moderate-intensity statin therapy based on patient risk factors. The stated rationale for removing LDL-C treatment targets is that no studies have focused on treatment or titration to a specific LDL-C goal in adults with clinical ASCVD. The majority of randomized controlled studies confirming the efficacy of cholesterol reduction in improving clinical outcomes in patients with clinical ASCVD used a single fixed-dose statin therapy to lower LDL-C levels.

The ADA Standards of Care has been updated each year since 2013, most recently in 2017. Each year there were several changes in the level of evidence and other minor changes that clarified recommendations or reflected new evidence. The 2017 version contained specific changes related to screening for diabetes and also modified the title of one of the sections from “Approaches to Glycemic Treatment” to “Pharmacologic Approaches to Glycemic Treatment” to reinforce that the section focuses on pharmacologic therapy alone.

- **Analysis:** The biennial review shows that the total number of beneficiaries meeting criteria for diabetes in the Medi-Cal fee-for-service beneficiaries has decreased considerably since the original DUR educational article. This is primarily driven by the decrease in the overall population of the Medi-Cal fee-for-service program in that same time period. However, within the study population there was less attrition seen in the number of beneficiaries with a comorbid mental health condition (decreased by 64.4%, vs. a decrease of 74.8% in the population without a comorbid mental health condition). Among beneficiaries with and without a comorbid mental health condition there was an increase in annual monitoring rates of HbA1C and LDL screening. The rates of HbA1C increased more since the original article than the rates of LDL screening, perhaps due to a change in the guidelines and metrics over time, as described above.

- **Limitations:** None.
• **Research/Policy Recommendations:**
  i. Continue to monitor clinical guidelines for updates and changes in standards of medical care in diabetes, including recommendations regarding therapeutic monitoring.
  ii. Continue to evaluate diabetes care performance measures using pharmacy and medical claims data from the Medi-Cal fee-for-service population, using targeted DUR educational outreach to providers and pharmacies, as needed.
  iii. Evaluate the use of basal insulin among diabetic Medi-Cal fee-for-service beneficiaries who have been on three non-insulin medications for at least three months.
  iv. Review the “Pharmacologic Approaches to Glycemic Treatment” section in the ADA’s Standards of Medical Care – 2017 and evaluate the Medi-Cal fee-for-service population to determine potential areas for improvement in the diabetes quality of care.

• **Clinical Recommendations:**
  1. Health care providers should evaluate patients diagnosed with diabetes to determine their understanding of their disease and educate patients about diabetic complications on a routine basis, even patients who have been living with diabetes for many years.
  2. Providers should advocate for patients to be more involved in self-management of diabetes, such as adherence to glucose monitoring and dieting.
  3. Establish a reminder system for patients regarding annual screenings.
  4. Mental health care providers should make sure that appropriate monitoring tests, including a fasting glucose test and full lipid profile are completed prior to initiation of second-generation atypical antipsychotic therapy and at regular intervals thereafter, as needed.
  5. All providers should incorporate psychological assessment and, if qualified, treatment into routine care.

- **Background:** On February 20, 2013, the U.S. Food and Drug Administration (FDA) issued a safety announcement regarding safety concerns with codeine use in certain children after tonsillectomy and/or adenoidectomy. Deaths have occurred post-operatively in children with obstructive sleep apnea who received codeine for pain relief following a tonsillectomy and/or adenoidectomy. These children had evidence of being ultra-rapid metabolizers of codeine, which is an inherited (genetic) ability that causes the liver to convert codeine into life-threatening or fatal amounts of morphine in the body. The FDA is modifying the drug label of codeine-containing products, including adding a new *Boxed Warning* about the risk of codeine in post-operative pain management in children following tonsillectomy and/or adenoidectomy.

- **Purpose:** The purpose of this biennial review is to review if there were any additional warnings or actions by the FDA regarding the risk of codeine in post-operative pain management in children following tonsillectomy and/or adenoidectomy since the original DUR alert was published in July 2013.

- **Data Criteria and Findings:** There were no additional FDA communications on this topic since the original drug safety communication on February 20, 2013.

- **Analysis:** Deaths have occurred in children with obstructive sleep apnea who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a cytochrome P450 2D6 (CYP2D6) polymorphism. These children may be particularly sensitive to the respiratory depressant effects of codeine that has been rapidly metabolized to morphine. Routine CYP2D6 genotype testing is not being recommended for use in this setting because patients with normal metabolism may, in some cases, convert codeine to morphine at levels similar to ultra-rapid metabolizers.

- **Limitations:** None.

- **Research/Policy Recommendations:**
  1. Continue to monitor FDA Drug Safety Communications for relevant alerts to the Medi-Cal fee-for-service population and providers.
• **Clinical Recommendations:**
  1. Health care professionals should prescribe an alternate analgesic for post-operative pain control in children who are undergoing tonsillectomy and/or adenoidectomy. Codeine should not be used for pain in children following these procedures.
  2. For management of other types of pain in children, codeine should only be used if the benefits are anticipated to outweigh the risks.
  3. If children are treated with codeine for other types of pain, monitor their respiratory status closely and advise parents/caregivers to monitor their children for signs of morphine overdose.

- **Background:** On May 6, 2013, the U.S. Food and Drug Administration (FDA) advised health care professionals and women that the anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium, are contraindicated and should not be taken by pregnant women for the prevention of migraine headaches. Valproate products have long been known to increase the risk of serious birth defects, in particular, neural tube defects such as spina bifida. In 2013, the Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) study also found evidence that children exposed to valproate products while their mothers were pregnant had decreased IQs at age 6 compared to children exposed to other anti-epileptic drugs.

- **Purpose:** The purpose of this biennial review is to review if there were any warnings or actions by the FDA regarding valproate use in pregnant women since the original DUR alert was published in July 2013.

- **Data Criteria and Findings:** There were no additional FDA communications on this topic since the original drug safety communication on May 6, 2013.

- **Analysis:** There is now evidence that valproate anti-seizure medications can cause decreased IQ scores in children whose mothers took them while pregnant. Stronger warnings about use during pregnancy will be added to the drug labels, and valproate’s pregnancy category for migraine use was changed from "D" (the potential benefit of the drug in pregnant women may be acceptable despite its potential risks) to "X" (the risk of use in pregnant women clearly outweighs any possible benefit of the drug).

- **Limitations:** None.

- **Research/Policy Recommendations:**
  1. Evaluate the use of valproate products among women of childbearing age in the Medi-Cal fee-for-service population, especially use for prevention of migraine headaches.
• **Clinical Recommendations:**
  1. Valproate products should not be used in pregnant women for prevention of migraine headaches.
  2. Valproate products should be used in pregnant women with epilepsy or bipolar disorder only if other treatments have failed to provide adequate symptom control or are otherwise unacceptable.
  3. Inform women of childbearing age of the increased risk for decreased IQ in children exposed to valproate products in utero and counsel them regarding the relative risks and benefits of valproate use, including the increased risk of other major structural and functional birth defects, particularly neural tube defects,
  4. Dietary folic acid supplementation should be routinely recommended both prior to conception and during pregnancy for patients taking valproate.
9. Improving the Quality of Care: Therapeutic Monitoring of Anticonvulsants – August 2013

- **Background:** Epilepsy is a neurological condition characterized by seizures, or temporary disturbances in nerve cells in the brain that result in excessive or abnormal electrical firing. Epilepsy is disproportionately represented in low-income populations, which have an increased incidence and prevalence of disabling physical and mental conditions that are known risk factors for epilepsy. Anticonvulsant medications are the most common approach to treat epilepsy and result in seizure control at least some of the time in 80 percent of patients. Annual monitoring of persistent medications, including anticonvulsants, was one of Medicaid’s initial core set of health care quality measures published in 2012. These quality measures were based on the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) persistent medications performance measures that evaluate the percentage of beneficiaries who received at least 180 days of certain anticonvulsants (phenytoin, phenobarbital, valproic acid, valproate sodium, divalproex sodium and carbamazepine) who had at least one therapeutic monitoring event for the prescribed drug. Drug serum concentration monitoring is recommended for certain anticonvulsants on at least an annual basis, as the dose alone may not be relied upon to predict the concentration of drug in the brain. In the original DUR article, the overall rate of drug serum concentration level monitoring tests among the Medi-Cal fee-for-service population with persistent medication use of anticonvulsant drugs was 56.6%, slightly lower than national averages.

- **Purpose:** The purpose of this biennial review is to review any updates to the clinical guidelines for therapeutic monitoring of anticonvulsants since the article was published and to re-examine monitoring rates in the Medi-Cal fee-for-service population, in order to determine if there have been any changes over time.

- **Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
  1. Inclusion criteria:
     i. Continuous eligibility for the Medi-Cal FFS program between January 1, 2016 and December 31, 2016 (the measurement year).
     ii. Between 18 and 64 years of age throughout the duration of the measurement year.
iii. At least 180 treatment days of one or more of the following anticonvulsant drugs: phenobarbital, carbamazepine, phenytoin, divalproex sodium, and/or valproic acid.

2. Exclusion criteria:
   i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 05/01/12 – 04/30/13</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries with at least 180 treatment days of an anticonvulsant medication during the measurement year</strong></td>
<td>8,907</td>
<td>5,140</td>
<td>-42.3%</td>
</tr>
<tr>
<td>Percentage of study population receiving at least 180 treatment days of more than one medication</td>
<td>10.1%</td>
<td>9.7%</td>
<td>-0.4%</td>
</tr>
<tr>
<td><strong>Overall unique events</strong></td>
<td>9,878</td>
<td>5,690</td>
<td>-42.4%</td>
</tr>
<tr>
<td>Annual monitoring rate</td>
<td>56.6%</td>
<td>56.9%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

Commencing with the release of the 2015 HEDIS® performance measures, the annual monitoring rate for anticonvulsants was retired. NCQA reported that the evidence demonstrates no benefit to routine drug concentration monitoring for patients on anticonvulsants who are responding to therapy. The biennial report used the same methods as in the original DUR article, but it is important to note that changes to this measure were implemented before the measurement year, which may have impacted why the annual monitoring rate remained almost stagnant over time.

- **Analysis:** Since the original article, the number of Medi-Cal fee-for-service beneficiaries with at least 180 treatment days of an anticonvulsant medication during the measurement year decreased by 42.3%, while the overall number of utilizing beneficiaries decreased by only 23.1%. In addition, among those beneficiaries with at least 180 treatment days of an anticonvulsant, the percentage of beneficiaries receiving at least 180 treatment days of more than one anticonvulsant decreased slightly (decreased by 0.4%). The annual monitoring rate went up by 0.3%, to 56.9%. When stratified by drug, the annual monitoring rates ranged from 51.5% for carbamazepine to 60.3% for phenytoin.
• **Limitations:** The original article did not specify the total utilizing beneficiaries with a paid claim for any of these drugs, so it cannot be determined if the changes in the total population with at least 180 treatment days is a factor of reduced adherence, reduced duration of treatment, or due to a change in overall beneficiaries using these drugs. Additionally, the original article did not breakdown the monitoring rate by drug, so it could not be determined if the rates stratified by drug were similar to those seen in the biennial review.

• **Research/Policy Recommendations:**
  1. Continue to monitor clinical guidelines for updates and changes in standards of medical care in epilepsy, including recommendations regarding therapeutic monitoring of anticonvulsants.
  2. Continue to evaluate performance measures related to epilepsy using pharmacy and medical claims data from the Medi-Cal fee-for-service population.
  3. Develop targeted DUR educational outreach to providers and pharmacies, as needed, based on performance measures.
  4. Evaluate the use of basal insulin among diabetic Medi-Cal fee-for-service beneficiaries who have been on three non-insulin medications for at least three months.

• **Clinical Recommendations:**
  1. Annual drug serum monitoring is recommended for all patients who have persistent use of anticonvulsants, even stabilized patients without co-morbid conditions.
  2. Measuring serum concentrations for patients on anticonvulsants is particularly important in order to guide dose adjustment for drugs that have dose-dependent pharmacokinetics, particularly phenytoin.
  3. Establish a reminder system for patients regarding annual monitoring.

- **Background:** Since 2010, ACIP has recommended annual influenza vaccination for all persons 6 months of age and older. Before the 2013 – 2014 influenza season, influenza vaccine was trivalent, containing three strains of virus: an influenza A (H3N2) strain, an influenza A (H1N1) strain and one influenza B strain. Starting in the 2013-14 influenza season, quadrivalent influenza vaccines containing an influenza A (H1N1) strain, an influenza A (H3N2) strain and two influenza B strains are available in some formulations of inactivated influenza vaccines and in all doses of live, attenuated influenza vaccine (nasal spray). Trivalent vaccine continues to be available for intramuscular and intradermal administration, as well as for all high-dose influenza vaccine for patients greater than 65 years of age. Also during 2013-14, vaccines produced by different manufacturing processes are also now available, with a recombinant vaccine produced in insect cell culture now licensed for patients ages 18 through 49 years of age and containing no egg protein. In addition, a vaccine produced in a mammalian cell culture line is now licensed for patients 18 years of age and older. While the cell culture vaccine is not produced in eggs, its seed virus is created using reference strains that have been passaged in eggs; its residual egg protein is estimated to be less than 5x10^-14 grams per dose.

- **Purpose:** The purpose of this biennial review is to review updates to the ACIP recommendations for influenza vaccine since the article was published.

- **Data Criteria and Findings:** This biennial review researched if there were any updates to ACIP recommendations on influenza vaccination since the original article, which was published in October 2013. For 2016-17 the ACIP recommendations for influenza vaccination of persons with egg allergy were modified. People with egg allergies can now receive any licensed, recommended age-appropriate influenza vaccine and no longer have to be monitored for 30 minutes after receiving the vaccine. People with severe egg allergies should be vaccinated in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic conditions. Also for the 2016-17 influenza season, in light of low effectiveness in the United States during the 2013–14 and 2015–16 seasons, ACIP made the recommendation that live, attenuated influenza vaccine (LAIV) should not be used. CDC only recommends use of the flu shot (inactivated influenza vaccine or IIV) and the recombinant influenza vaccine (RIV) during 2016-17.
• **Analysis:** Influenza viruses may cause illness in persons of all ages, with annual influenza epidemics generally occurring during the fall or winter months in the United States. Vaccination is the primary means of preventing influenza and its complications, which may range from missed days from school and work to hospitalization and death. Trivalent vaccines contain three strains of virus: an influenza A (H3N2) strain, an influenza A (H1N1) strain and one influenza B strain. Influenza B viruses emerge from two distinct lineages and typically viruses from both lineages co-circulate, therefore the absence of a second B strain has been a limitation of the influenza vaccine. During the last ten influenza seasons, the most common circulating influenza B virus matched the B virus in the trivalent vaccine for only 50 percent of the seasons. Potentially, the addition of a second influenza B virus will increase the protective effects of the vaccine.

• **Limitations:** None.

• **Research/Policy Recommendations:**
  1. Continue to educate patients and providers about the importance of annual influenza vaccination for anyone 6 months of age and older.
  2. Work with CDPH to promote that all ACIP-recommended adult immunizations are now available as a Medi-Cal pharmacy benefit.
  3. Consider targeted outreach regarding influenza vaccination to providers who treat Medi-Cal fee-for-service beneficiaries. Reaching out to providers may help determine barriers and facilitators to vaccination in this population.

• **Clinical Recommendations:**
  1. All prescribers and pharmacies should review immunization status and other evidence of immunity to vaccine-preventable diseases for all patients.
  2. All health care providers should routinely encourage flu vaccine for all patients 6 months of age and older.
  3. All health care providers should feel comfortable addressing myths about influenza and the influenza vaccine.

- **Background:** Early evidence suggests that vaccinating pregnant women with tetanus toxoid, reduced diphtheria toxoid and cellular pertussis vaccine (Tdap) in the third trimester can prevent pertussis in young infants through maternal antibodies transferred through the placenta. Optimal timing for Tdap administration in pregnant women is between 27 and 36 weeks gestation. In October 2012, ACIP updated their recommendations for the use of tetanus toxoid, reduced diphtheria toxoid and Tdap in pregnant women. Pregnant women are now recommended to receive a dose of Tdap with every pregnancy, irrespective of their prior history of receiving Tdap. If Tdap is not administered during pregnancy, it should be administered immediately postpartum. This will not provide direct protection to the infant, but may prevent transmission of pertussis from mother to infant. Similarly, those in contact with infants should also receive the Tdap vaccine if they have not already done so.

- **Purpose:** The purpose of this biennial review is to determine if there have been any updates to the ACIP recommendations for pertussis vaccine since the original DUR educational article was published in November 2013.

- **Data Criteria and Findings:** Since January 2016, there have been 37 cases of pertussis in California among infants younger than 4 months of age. Twelve of the mothers who had babies who later developed pertussis had not been vaccinated during pregnancy. When interviewed in more detail, six of them did not remember a provider recommendation and five reported refusing provider recommendations. This suggests more focus should be put into provider and patient education about the significance of prenatal Tdap vaccination. Postpartum Tdap vaccination and cocooning are no longer considered optimal strategies to prevent pertussis in infants.

- **Analysis:** Young infants are at greatest risk of hospitalization and death from pertussis, therefore pregnant women are encouraged to receive pertussis vaccine (Tdap) during the 3rd trimester of every pregnancy. Pertussis antibodies are transferred from vaccinated mothers to their infants and will help protect them until they are old enough to be vaccinated. The primary DTaP vaccine series is essential for reducing severe disease in young infants and should not be delayed. DTaP can be given to infants at an accelerated schedule with the first dose given as early as 6 weeks of age. Even one dose of DTaP may offer some protection against severe pertussis disease and death in infants.
• **Limitations:** None.

• **Research/Policy Recommendations:**
  1. Continue to monitor ACIP recommendations for updates to vaccine guidelines and policy.
  2. Collaborate with key stakeholders, including other state agencies, to educate providers and patients about the significance of prenatal Tdap vaccination.
  3. Work with CDPH to promote that all ACIP-recommended adult immunizations are now available as a Medi-Cal pharmacy benefit.

• **Clinical Recommendations:**
  1. Educate patients about the significance of prenatal Tdap vaccination.
  2. Routinize the offer of prenatal Tdap for all pregnant women at the beginning of the third trimester to protect babies who might be born prematurely. Consider combining Tdap vaccination with the glucose screening test at 28 weeks and/or calling your electronic health record (EHR) vendor to request a flag that automatically reminds you to offer the vaccination to all prenatal patients.
  3. Visit the CDPH website to stay informed on pertussis outbreaks.
**Background:** While there is no cure for asthma, patient education regarding medication use, symptom management, and avoidance of asthma attack triggers can greatly reduce the impact of the disease. Inhaled corticosteroids are the preferred long-term controller therapy for asthma across all ages, but despite overwhelming evidence supporting the efficacy of long-term controller medications, adherence is low nationwide, with only one-third of children or adults with asthma using long-term control medicine as prescribed. The 2013 HEDIS performance indicators for the first time include a measure evaluating the asthma medication ratio (AMR), which is defined as the percentage of members 5–64 years of age with persistent asthma who had a ratio of controller medications to total asthma medications (controller plus reliever) of 0.50 or greater during the measurement year. The AMR has been reported as a more effective assessment of asthma quality of care and a more reliable predictor of patient outcomes, asthma-related hospitalizations and emergency department utilization. Within the Medi-Cal fee-for-service population the overall rate of beneficiaries with an AMR ≥ 0.50 was 57.3 percent, which appear similar to what was found during the pilot-testing of the measure (61.6% overall in a national commercial insurance population and 51.9% in a national Medicaid population).

**Purpose:** The purpose of this biennial review is to re-evaluate the use of asthma controller and reliever medications in the Medi-Cal fee-for-service population, in order to determine if there have been any changes in use and prescribing patterns over time.

**Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:

1. **Inclusion criteria:**
   i. Persistent asthma, as defined by the parameters for the HEDIS® AMR performance measure, during both the measurement year (January 1, 2016 and December 31, 2016) and the year prior
   ii. Between 5 and 64 years of age throughout the duration of the measurement year.

2. **Exclusion criteria:**
   i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.
   ii. Beneficiaries with any diagnosis code for emphysema, chronic obstructive pulmonary disease (COPD), cystic fibrosis or acute respiratory failure.
<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 09/01/12 – 08/31/13</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries identified with persistent asthma during both the measurement year and the year prior to the measurement year that meet inclusion/exclusion criteria for the study population</strong></td>
<td>25,209</td>
<td>7,112</td>
<td>-71.8%</td>
</tr>
<tr>
<td>Percentage with ≥ 1 one acute inpatient claim/encounter with asthma as the principal diagnosis during the measurement year</td>
<td>1.2%</td>
<td>0.2%</td>
<td>-1.0%</td>
</tr>
<tr>
<td>Percentage with at ≥ 4 outpatient asthma visits and ≥ 2 asthma medication dispensings during the measurement year</td>
<td>2.1%</td>
<td>2.0%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Percentage with ≥ 1 emergency department visit with asthma as the principal diagnosis during the measurement year</td>
<td>2.4%</td>
<td>1.2%</td>
<td>-1.2%</td>
</tr>
<tr>
<td>Percentage with ≥ 4 asthma medication dispensings during the measurement year</td>
<td>98.8%</td>
<td>96.0%</td>
<td>-2.8%</td>
</tr>
<tr>
<td>Percentage with no paid claims for any asthma medication during the measurement year (excluded from the asthma medication ratio calculation)</td>
<td>0.6%</td>
<td>0.4%</td>
<td>-0.2%</td>
</tr>
<tr>
<td><strong>Beneficiaries included in the asthma medication ratio calculation</strong></td>
<td>25,058</td>
<td>7086</td>
<td>-71.7%</td>
</tr>
<tr>
<td>Percentage with an asthma medication ratio ≥ 0.50</td>
<td>60.6%</td>
<td>69.7%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

Commencing with the release of the 2016 HEDIS® performance measures, there were some modifications made to this measure. For this measure, NCQA has expanded the age range to include people aged 5 to 85 (up from 5 to 64). In addition, one of the other asthma measures, “Use of Appropriate Medications for People with Asthma” was retired because the measure, “Medication
Management for People with Asthma” was determined to be more effective in assessing asthma medication management.

- **Analysis:** While there study population decreased by 71.8% from the original article to the biennial review, the two study populations were very similar with regards to the beneficiaries within each study population, with the cohort from the biennial review doing slightly better on markers that measure quality-of-care in asthma. Within the biennial review cohort, there was a decrease in the percentage of the study population that had an inpatient or an emergency department visit for asthma and a decrease in the percentage with greater than four asthma medication dispensings. Finally, the percentage with an AMR ≥ 0.50 increased by 9.1%, which means more reliever medications are being prescribed relative to controller medications in the Medi-Cal fee-for-service asthma population.

- **Limitations:** The original article did not specify within the inclusion criteria that beneficiaries had to be continuously—eligible in the Medi-Cal fee-for-service for either the duration of the measurement year and/or for the year prior to the measurement year. For the biennial review, continuous eligibility was determined by using the most recent 16 months of data (all that is available) after the above inclusion/exclusion criteria were applied. The addition of continuous-eligibility requirements decreased the study population from 13,675 beneficiaries to 7,112 beneficiaries, but allowed for a more rigorous data collection method and meaningful results.

- **Research/Policy Recommendations:**
  1. Continue to monitor clinical guidelines for updates and changes in standards of medical care in asthma.
  2. Continue to evaluate asthma performance measures using pharmacy and medical claims data from the Medi-Cal fee-for-service population.
  3. Continue using targeted DUR educational outreach to providers and pharmacies, as needed, to address patient-level quality-of-care issues.
  4. Regularly evaluate the use of reliever and controller medications among Medi-Cal fee-for-service beneficiaries who have been diagnosed with asthma.
• **Clinical Recommendations:**
  1. A stepwise approach to managing asthma is recommended to gain and maintain control of asthma in both the impairment and risk domains.
  2. Provide inhaled corticosteroids at discharge following an inpatient admission or emergency department visit for an asthma exacerbation.
  3. Assess patients for chronic rhinitis or gastroesophageal reflux disease, which may exacerbate asthma symptoms.
  4. Encourage/remind patients with asthma and others at risk to receive annual influenza vaccinations.
  5. Assist patients with asthma (or their parents and close family members) in smoking cessation, by providing patient educational materials regarding the health hazards of smoking and second-hand smoke and appropriate smoking cessation techniques.
  6. Provide a written asthma action plan in lay language to all patients.
**Background:** Patients with diabetes mellitus type 2 have been shown to have an impaired incretin response, which has led to the development of a novel class of drugs called the incretin-based therapies. Dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors) and glucagon-like peptide-1 receptor agonists (GLP-1 agonists) are the two available incretin based therapies. Incretin therapy is used to improve diabetes control and increase weight loss, either alone or in conjunction with other medications such as metformin or insulin. Recent epidemiologic studies, animal studies and autopsy studies have raised concerns that incretin-based therapies may be associated with pancreatic changes ranging from pancreatitis to premalignant lesions. On June 28, 2013, the American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation issued updated recommendations for clinicians and patients with diabetes concerning the use of incretin therapy and pancreatic disease.

**Purpose:** The purpose of this biennial review is to review if there were any updates concerning the use of incretin therapy and pancreatic disease since the original DUR alert was published in January 2014.

**Data Criteria and Findings:** There were no updated recommendations by the American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation concerning the use of incretin therapy and pancreatic disease since the June 28, 2013 statement. In February 2014, an article was published in the *New England Journal of Medicine* that shared perspectives from both the FDA and the European Medicines Agency (EMA). The article stated that the FDA and the EMA have explored multiple streams of data pertaining to a pancreatic safety signal associated with incretin-based drugs. Both agencies agreed that assertions concerning a causal association between incretin-based drugs and pancreatitis or pancreatic cancer are inconsistent with the current data and they have not reached a final conclusion regarding a causal relationship. In 2016, results from a large, randomized controlled trial were published and the authors concluded that the use of incretin based drugs was not associated with an increased risk of pancreatic cancer compared with sulfonylureas. Recent meta-analyses have also found similar results.
• **Analysis:** While recent clinical research provides reassurance, pancreatitis will continue to be considered a risk associated with these drugs until more data are available. The FDA believes that the current knowledge is adequately reflected in the product labeling and they continue to review the ongoing systematic capture of data on pancreatitis and pancreatic cancer from cardiovascular outcome trials and ongoing clinical trials, which should facilitate meta-analyses, and accumulation of further knowledge.

• **Limitations:** None.

• **Research/Policy Recommendations:**
  1. Continue to review literature and drug safety information for potential medication safety issues relevant to the Medi-Cal fee-for-service population and providers.

• **Clinical Recommendations:**
  2. Diabetes care providers should consider any potential adverse effects as they balance risk and benefit of particular treatment paradigms, especially in patients with other risk factors for pancreatitis.
  3. Discourage patients from stopping medications on their own without consulting their health care provider, since this can lead to higher levels of blood glucose that may cause serious short-term health problems and if prolonged, could increase the risk of long term diabetes-related complications.

- **Background:** For all patients presenting with cough, a thorough medical history and physical examination is the best starting point to determine whether the patient is receiving an angiotensin-converting enzyme (ACE) inhibitor, is a smoker, or has evidence of a serious life-threatening or systemic disease. The American College of Chest Physicians (ACCP) developed clinical guidelines that outline a systematic, integrated approach for clinicians trying to classify, evaluate and treat unexplained cough. A comparative effectiveness review by the Agency for Healthcare Research and Quality (AHRQ) looked at commonly used therapies in the United States for symptomatic treatment of chronic cough. The AHRQ findings showed evidence of relative efficacy for the reduction of frequency and severity of chronic cough for codeine and dextromethorphan, in comparison to placebo, however, could not draw conclusions about the comparative effectiveness of these two agents. The original DUR educational article evaluated the use of antitussives in the Medi-Cal fee-for-service population, including a more in-depth review of promethazine with codeine due to an increase in reports of promethazine abuse in combination with opioids. While the majority (81.0%) of Medi-Cal fee-for-service beneficiaries had only one or two paid claims for this drug during a one-year time period, 377 beneficiaries (0.1%) had paid claims for promethazine with codeine cough syrup in amounts greater than 5,760 ml (5,760 ml = one 480 ml bottle every month for 12 months).

- **Purpose:** The purpose of this biennial review is to re-evaluate the use of promethazine with codeine cough syrup in the Medi-Cal fee-for-service population, in order to determine if there have been any changes in use and prescribing patterns over time.

- **Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
  1. **Inclusion criteria:**
     i. Had at least one paid pharmacy claim for promethazine with codeine cough syrup between January 1, 2016 and December 31, 2016.

  2. **Exclusion criteria:**
     i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.
<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 08/01/12 – 07/31/13</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries identified with at least one paid claim for promethazine with codeine cough syrup</strong></td>
<td>67,706</td>
<td>24,878</td>
<td><strong>-63.3%</strong></td>
</tr>
<tr>
<td><strong>Percentage with 2 or less paid claims for promethazine with codeine cough syrup during the measurement year</strong></td>
<td>81.0%</td>
<td>84.9%</td>
<td><strong>3.9%</strong></td>
</tr>
<tr>
<td><strong>Percentage with 6 or more paid claims for promethazine with codeine cough syrup during the measurement year</strong></td>
<td>6.9%</td>
<td>5.5%</td>
<td><strong>-1.4%</strong></td>
</tr>
<tr>
<td><strong>Beneficiaries identified with paid claims ≥ 5,760 ml of promethazine with codeine cough syrup during the measurement year</strong></td>
<td>377</td>
<td>58</td>
<td><strong>-84.6%</strong></td>
</tr>
<tr>
<td><strong>Beneficiaries identified that averaged greater than 30ml/day of promethazine with codeine cough syrup during the entire measurement year</strong></td>
<td>51</td>
<td>&lt; 10</td>
<td>≥ <strong>-82.4%</strong></td>
</tr>
</tbody>
</table>

Since the original article was published in March 2014, a restriction has been added to promethazine with codeine. Effective July 1, 2014, promethazine with codeine is restricted to a maximum dispensing quantity of 360 ml and a maximum of three (3) dispensings in any 75-day period.

- **Analysis:** There was a 63.3% decrease in the number of beneficiaries identified with a paid claim for promethazine with codeine cough syrup. This decrease far exceeds the difference in both the number of eligible beneficiaries during this same time period (a decrease of 8.1%) and the number of utilizing beneficiaries (a decrease of 21.7%). Reductions were even greater among high utilizers of promethazine with codeine, with an 84.6% decrease in the number of beneficiaries with paid claims ≥ 5,760 ml during the measurement year and at least an 82.4% decrease in beneficiaries that averaged greater than 30ml/day of promethazine with codeine cough syrup during the entire measurement year.

- **Limitations:** In the current Medi-Cal fee-for-service population, antitussive medications are consistently one of the top utilized drugs in the 65 years of age and older population. Between August 1, 2012 (the beginning of the measurement year from the original article), and December 31, 2016 (the end of the measurement year in this biennial review), the number of utilizing...
beneficiaries in this age group decreased by 70.0%, which may be skewing the utilization data for promethazine with codeine. The original article did not have a breakdown of utilization by age and drug, but did report the range of antitussive use in this age group ranged from 11% to 28% of the population, depending on the drug, higher than all other age groups.

- **Research/Policy Recommendations:**
  1. Continue to monitor use of antitussives within the Medi-Cal fee-for-service population.
  2. Consider DUR educational outreach to top prescribers of opiate antitussive therapy.
  3. Consider increasing the age restriction or opiate antitussive therapy from less than 2 years of age to less than 6 years of age, per clinical guidelines.
  4. Consider adding quantity restrictions for promethazine with phenylephrine and codeine cough syrup, similar to the restrictions for promethazine with codeine cough syrup/
  5. Consider restrictions on indications of use and/or duration of use for opiate antitussive therapy.

- **Clinical Recommendations:**
  1. For all patients presenting with cough, a thorough medical history and physical examination is the best starting point to determine whether the patient is receiving an ACE inhibitor, is a smoker, or has evidence of a serious life-threatening or systemic disease.
  2. For adults and adolescents 15 years of age and older with chronic cough and normal chest radiography, empiric treatment should be initiated in sequential and additive steps targeting the most common causes of chronic cough (i.e., upper airway cough syndrome, asthma, and gastroesophageal reflux disease).
  3. The use of antitussive medications is most appropriate when (1) the etiology of cough is unknown (precluding the use of specific therapy), (2) specific therapy requires a period of time before it can become effective, or (3) specific therapy will be ineffective, such as in patients with inoperable lung cancer.
  4. Recognize the side effect profile of opiate antitussive therapy – in particular, codeine and promethazine cough syrup – includes the potential for abuse and addiction and should be used sparingly as a first-line therapy.
5. Evaluation of children younger than 15 years of age with a chronic cough lasting longer than four weeks should include, at minimum, chest radiography and spirometry.

6. Provide guidance and education to parents and caregivers on the appropriate use (or nonuse) of cough and cold medications in children, including information on viable nonpharmacological alternatives, such as cool mist humidifiers and vaporizers, and honey in children older than 1 year of age.
Improving the Quality of Care: Appropriate Monitoring of Medication Therapy – May 2014

- **Background:** Appropriate monitoring of medication therapy can be a significant tool to help guide therapeutic decision-making. Persistent use of certain medications warrants monitoring and follow-up by the prescribing provider to assess for side effects and to make adjustments to the drug regimen. Regular monitoring also provides opportunities for improvement in care for patients who use certain medications for extended periods of time. Costs associated with annual monitoring are offset by the reduction in health care costs associated with complications arising from lack of monitoring and follow-up of patients on long-term medications. Annual monitoring for patients on persistent medications, including ACE inhibitors or ARBs, diuretics, and digoxin, continues to be one of Medicaid’s core set of health care quality measures. The annual monitoring for patients on persistent medications measure evaluates the percentage of beneficiaries who received at least 180 treatment days of ACE inhibitors or ARBs, diuretics, and/or digoxin over a 12-month period who received an annual assessment of serum potassium and renal function (serum creatinine or blood urea nitrogen). In the original DUR article, the overall rate of serum potassium and either serum creatinine or blood urea nitrogen therapeutic monitoring tests among the Medi-Cal fee-for-service population ranged from 80 percent among those beneficiaries with persistent medication use of ACE inhibitors or ARBs to 82 percent among those beneficiaries with persistent use of diuretics and/or digoxin. Overall monitoring rates for each drug class were within range of published averages and the rate for annual monitoring for beneficiaries with persistent use of diuretics was higher among the Medi-Cal fee-for-service population in comparison to the Medi-Cal Managed Care population.

- **Purpose:** The purpose of this biennial review is to review any updates to the clinical guidelines for therapeutic monitoring of persistent medications since the article was published and to re-examine monitoring rates in the Medi-Cal fee-for-service population, in order to determine if there have been any changes over time.

- **Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
  1. Inclusion criteria:
     i. Continuous eligibility for the Medi-Cal FFS program between January 1, 2016 and December 31, 2016 (the measurement year).
ii. Between 18 and 64 years of age throughout the duration of the measurement year.

iii. At least 180 treatment days with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), diuretics, and/or digoxin during the measurement year.

2. Exclusion criteria:
   i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare.

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 10/01/12 – 09/30/13</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries identified with at least 180 treatment days with an ACE inhibitor or ARB during the measurement year</strong></td>
<td>16,378</td>
<td>21,454</td>
<td>31.0%</td>
</tr>
<tr>
<td>Percentage with a paid claim for monitoring during the measurement year</td>
<td>80%</td>
<td>84%</td>
<td>4.0%</td>
</tr>
<tr>
<td><strong>Beneficiaries identified with at least 180 treatment days with a diuretic during the measurement year</strong></td>
<td>10,327</td>
<td>9,753</td>
<td>-5.6%</td>
</tr>
<tr>
<td>Percentage with a paid claim for monitoring during the measurement year</td>
<td>82%</td>
<td>85%</td>
<td>3.0%</td>
</tr>
<tr>
<td><strong>Beneficiaries identified with at least 180 treatment days with digoxin during the measurement year</strong></td>
<td>628</td>
<td>367</td>
<td>-6.4%</td>
</tr>
<tr>
<td>Percentage with a paid claim for monitoring tests during the measurement year</td>
<td>82%</td>
<td>86%</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

Commencing with the release of the 2015 HEDIS® performance measures, there were some modifications made to this measure. For monitoring patients with persistent use of ACE inhibitors or ARBs, diuretics or digoxin, NCQA reported that the evidence continues to support annual monitoring of serum creatinine and serum potassium to reduce potentially fatal risks associated with the use of these medications. However, there was no evidence on the utility of using blood urea nitrogen to monitor renal function, so this was removed from the measure. In addition, evidence from multiple clinical trials supported annual monitoring of serum digoxin concentration level, to avoid potential digoxin toxicity, so this was added to the measure. The biennial report used the same methods as in the original DUR article, but it is important to note that changes to this measure were implemented before the measurement year, which may have impacted performance metrics.
• **Analysis:** Despite a decrease in the total number of utilizing beneficiaries in the Medi-Cal fee-for-service program, there has been a large increase in the number of utilizing beneficiaries with paid claims for at least 180 treatment days with an ACE inhibitor or ARB, up 31% since the original DUR article was published. In comparison, the total numbers of utilizing beneficiaries with paid claims for at least 180 treatment days of diuretics and/or digoxin decreased during this same timeframe. Monitoring rates for all three classes of drugs increased since the original article, with monitoring rates now between 84% and 86%. While these rates are an across-the-board improvement from the original article, they still fall just under the minimum performance level established by DHCS.

• **Limitations:** The original article did not specify the total utilizing beneficiaries with a paid claim for any of these drugs, so it cannot be determined if the changes in the total population with at least 180 treatment days is a factor of improved adherence or change in overall beneficiaries using these drugs.

• **Research/Policy Recommendations:**
  1. Continue to evaluate performance measures related to therapeutic monitoring using pharmacy and medical claims data from the Medi-Cal fee-for-service population.
  2. Develop targeted DUR educational outreach to providers and pharmacies, as needed, based on performance measures.

• **Clinical Recommendations:**
  1. When prescribing a new drug or making adjustments to a drug regimen educate patients about the anticipated benefits and possible problems associated with the drug and the purpose of laboratory monitoring
  2. After prescribing a new drug, continually assess drug effectiveness, adverse events, medication adherence and whether the drug is still needed. If the regimen needs to be adjusted, use that opportunity to re-educate patients about the importance of adherence to therapy and monitoring.
  3. Require laboratory monitoring a minimum of once yearly for prescription refills
  4. Establish a reminder system for patients regarding annual monitoring.
16. In the News: Prescription Drug Abuse and Diversion of Controlled Substances – August 2014

- **Background:** Since the mid-1990s, misuse of prescription drugs has emerged as a serious threat to public health in the United States. Every pharmacist who fills a prescription for a controlled substance must exercise professional judgment to determine that the prescription has been issued for a legitimate medical reason and must be increasingly diligent and document efforts to identify and resolve certain red flags before dispensing a prescription for controlled substances. Once they are prescribed and dispensed, prescription drugs are frequently diverted to people using them without prescriptions, with more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else. According to the 2013 National Drug Threat Assessment report, the threat posed by the diversion and abuse of controlled prescription drugs places a considerable burden on law enforcement and public health resources. Finally, the fiscal impact of prescription drug abuse and drug diversion on the Medicaid program extends beyond the cost of beneficiaries’ prescription drugs, which reached almost $20 billion in 2012 alone. When patients misuse prescription drugs there are added costs including additional doctor’s visits, emergency department treatment, rehabilitation centers and other health care needs. A review of claims data in the original DUR article showed that of the top 20 controlled substances by total utilizing beneficiaries, eleven drugs were opioids, three were anxiolytics, three were sedatives, and four were stimulants. For the most part, rates of multiple claims (greater than one or two claims per month) and multiple prescribers (greater than two prescribers) were low among controlled substances, with only phenobarbital showing greater than 10% of utilizing beneficiaries having more than one claim per month for the measurement year. The majority (64%) of Medi-Cal fee-for-service beneficiaries with a paid claim for prescription opioids had only one paid claim for prescription opioids during the measurement year; however, 16% of Medi-Cal fee-for-service beneficiaries had paid claims for prescription opioids from more than one prescriber. Prescribers and pharmacists should be aware of red flags that may indicate prescription drugs are being abused or diverted.

- **Purpose:** The purpose of this biennial review is to re-evaluate the use of controlled substances identified as targets for drug diversion within the Medi-Cal fee-for-service population, in order to determine if there have been any changes in use and prescribing patterns over time.
Data Criteria and Findings: For the biennial review, the same inclusion/exclusion criteria as the published article were followed. The only inclusion criteria from the original article was that a beneficiary had to have at least one pharmacy claim for a DEA scheduled medication (schedules II - V) during the measurement year paid through the Medi-Cal fee-for-service program. For the biennial review, the measurement year was calendar year 2016 (between January 1, 2016, and December 31, 2016).

<table>
<thead>
<tr>
<th>Medi-Cal fee-for-service population</th>
<th>Article data: 04/01/13 – 03/31/14</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Eligible Beneficiaries</td>
<td>2,661,337</td>
<td>2,435,932</td>
<td>-8.5%</td>
</tr>
<tr>
<td>Total Utilizing Beneficiaries</td>
<td>535,696</td>
<td>411,878</td>
<td>-23.1%</td>
</tr>
<tr>
<td>Beneficiaries with ≥ 1 paid claim for any scheduled medication</td>
<td>337,174</td>
<td>319,466</td>
<td>-5.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage with ≥ 1 paid claim for:</th>
<th>RANK (by utilizing beneficiaries)</th>
<th>TOTAL utilizing beneficiaries</th>
<th>RANK (by utilizing beneficiaries)</th>
<th>TOTAL utilizing beneficiaries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone/acetaminophen</td>
<td>1</td>
<td>150,715</td>
<td>1</td>
<td>131,861</td>
</tr>
<tr>
<td>Promethazine/codeine</td>
<td>2</td>
<td>56,038</td>
<td>4</td>
<td>24,012</td>
</tr>
<tr>
<td>Codeine/acetaminophen</td>
<td>3</td>
<td>44,037</td>
<td>2</td>
<td>45,782</td>
</tr>
<tr>
<td>Tramadol</td>
<td>4</td>
<td>38,040</td>
<td>3</td>
<td>34,900</td>
</tr>
<tr>
<td>Guaifenesin/codeine</td>
<td>5</td>
<td>37,399</td>
<td>6</td>
<td>20,082</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>6</td>
<td>29,049</td>
<td>5</td>
<td>23,164</td>
</tr>
<tr>
<td>Oxycodone/acetaminophen</td>
<td>7</td>
<td>21,909</td>
<td>7</td>
<td>19,720</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>8</td>
<td>16,799</td>
<td>11</td>
<td>8,705</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>9</td>
<td>15,807</td>
<td>9</td>
<td>10,101</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>10</td>
<td>6,970</td>
<td>13</td>
<td>4,711</td>
</tr>
<tr>
<td>Diazepam</td>
<td>11</td>
<td>6,840</td>
<td>10</td>
<td>8,834</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>12</td>
<td>6,357</td>
<td>12</td>
<td>7,826</td>
</tr>
<tr>
<td>Lisdexamfetamine</td>
<td>13</td>
<td>6,321</td>
<td>15</td>
<td>3,929</td>
</tr>
<tr>
<td>Dextroamphetamine/amphetamine</td>
<td>14</td>
<td>6,254</td>
<td>14</td>
<td>4,171</td>
</tr>
<tr>
<td>Temazepam</td>
<td>15</td>
<td>5,653</td>
<td>17</td>
<td>3,119</td>
</tr>
<tr>
<td>Morphine</td>
<td>16</td>
<td>5,083</td>
<td>21</td>
<td>2,530</td>
</tr>
<tr>
<td>Dexamphetamine</td>
<td>17</td>
<td>4,676</td>
<td>22</td>
<td>2,372</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>18</td>
<td>4,079</td>
<td>20</td>
<td>2,636</td>
</tr>
<tr>
<td>Methadone</td>
<td>19</td>
<td>3,502</td>
<td>27</td>
<td>1,210</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>20</td>
<td>3,335</td>
<td>23</td>
<td>2,128</td>
</tr>
</tbody>
</table>
### Table: Medi-Cal fee-for-service population

<table>
<thead>
<tr>
<th></th>
<th>Article data: 04/01/13 – 03/31/14</th>
<th>Biennial review data: 01/01/16 – 12/31/16</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiaries with at least one paid claim for an opioid medication</strong></td>
<td>319,389</td>
<td>257,700</td>
<td>-19.3%</td>
</tr>
<tr>
<td>Percentage with only one paid claim for an opioid medication</td>
<td>64.2%</td>
<td>71.7%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Percentage with paid claims for opioids from only one prescriber</td>
<td>83.9%</td>
<td>88.8%</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

Since the publication of the original article in August 2014, the following federal and state policy changes may have impacted the utilization of scheduled medications in the Medi-Cal fee-for-service population:

1. Effective October 6, 2014 the DEA rescheduled hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act.
2. Effective June 1, 2015, Medi-Cal no longer requires an approved Treatment Authorization Request (TAR) for buprenorphine.
3. Effective July 1, 2016, methadone was suspended from the Medi-Cal List of Contract Drugs.

**Analysis:** The biennial review shows that the total number of Medi-Cal fee-for-service beneficiaries with a paid claim for a scheduled medication has decreased by 5.3% since the original DUR educational article. Of note, the overall population of Medi-Cal fee-for-service beneficiaries has decreased since the original DUR educational article was written, which may account for the smaller study population. However, even given the overall reduction in population, there were decreases in paid claims for certain drugs within the Top 20 drugs by total utilizing beneficiaries that exceeded the average reduction in the population as a whole. For example, the total utilizing beneficiaries with a paid claim for opiate antitussive therapy (promethazine with codeine and guaifenesin with codeine) decreased by about half. The greatest decrease was in the total utilizing beneficiaries with a paid claim for methadone, which posted a 65.4% decrease in the number of utilizing beneficiaries since the original article, which may be explained by being suspended from the Medi-Cal List of Contract Drugs in July 2016. Three of the top 20 drugs by total utilizing beneficiaries did post increases in comparison to the original article: diazepam, oxycodone, and codeine with acetaminophen. A previous DUR retrospective review found the timing of the increase in utilizing beneficiaries with a paid claim for codeine with acetaminophen corresponded to the rescheduling of hydrocodone with acetaminophen effective October 6, 2014. In addition, among all beneficiaries...
with at least one paid claim for an opioid, the percentage of beneficiaries with only one paid claim for an opioid during the measurement year increased by 7.5% to 71.7% and the percentage with paid claims for opioids from only one prescriber also increased by 4.9% from the original article, going from 83.9% to 88.8%. Of note, when utilization data were stratified by drug, 12 of the top 20 drugs had decreases in the percentage of utilizing beneficiaries with greater than two prescribers. However, all four drugs in the stimulant class posted increases in the percentage of beneficiaries with more than two prescribers in comparison to the original article, while phenobarbital, hydromorphone, morphine, and methadone accounted for the other four drugs that posted increases.

- **Limitations:** The original DUR article was intended to be a general overview of utilization of controlled substances in the Medi-Cal fee-for-service population, and the same is true for this biennial review. The limitations of these data include the following: 1) these data are based only on total paid claims instead of by quantity, so a utilizing beneficiary could have multiple prescriptions for small quantities of controlled substances; and 2) prescribers at the same site were not excluded, so if a patient saw different prescribers from the same practice it may appear they were receiving controlled substances by multiple providers, even when care has been coordinated within one location. In addition, this overview does not contain important patient-specific data related to diagnostic codes and other concomitant medications that may better inform whether prescribing of controlled substances is therapeutically appropriate and medically indicated and polypharmacy of multiple controlled substances by Medi-Cal beneficiaries was not addressed.

- **Research/Policy Recommendations:**
  1. Continue to monitor the use of opioids and other controlled medications in the Medi-Cal fee-for-service population.
  2. Continue to assess the need for additional policy restrictions on opioids, including maximum quantity and duration restrictions and recent age restrictions.
  3. Continue to assess the impact of federal and state policy restrictions on use of opioids and other controlled medications.
  4. Continue to collaborate with state agencies like the Board of Pharmacy and the Audits & Investigations Branch to combat prescription drug abuse and diversion.
  5. Continue to develop targeted DUR educational outreach to providers and pharmacies, as needed, to promote responsible prescribing of controlled substances.
**Clinical Recommendations:**

1. All health care providers should be aware of red flags that may indicate prescription drugs are being abused or diverted. Prescribe and dispense controlled medications only for appropriate patients and indications.

2. Pharmacies should encourage all pharmacy staff to view the educational video entitled “Red Flags”, which may be found on the National Association of Boards of Pharmacy (NABP) website at [http://www.nabp.net/](http://www.nabp.net/).


4. Counsel patients on safe use of opioids, including where and when to dispose of opioids and other prescription drugs. Encourage all patients to participate in National Prescription Drug Take-Back Days, in order to dispose of expired, unused, and unwanted prescription drugs.

5. Encourage patients who require opioids for pain control to keep their medications under strict control and not give unused medication to family or friends.

6. As needed, provide naloxone kits to patients and/or caregivers to help avert accidental overdose from opioids.
**Background:** Commencing with this DUR educational bulletin, the California Medi-Cal Drug Use Review program began consolidating updates in immunization guidelines, products, and/or research into an annual summary. This 2014 summary included influenza, Tdap, and human papillomavirus (HPV) immunization updates. For the 2014-2015 influenza season, ACIP recommended the use of live attenuated influenza vaccine (LAIV), when immediately available, for healthy children aged two through eight years without contraindications or precautions to the vaccine. As for Tdap, at the time of the bulletin California was experiencing a pertussis epidemic so it was a high priority for CDPH to continually promote that Tdap is recommended during each and every pregnancy, optimally between 27 and 36 weeks gestation. Finally, on July 25, 2014, CDC reported data from the 2007 – 2013 National Immunization Survey-Teen (NIS-Teen) and national post-licensure vaccine safety data for HPV vaccine. In the United States, vaccination coverage with at least one dose of HPV vaccine increased from 54% (2012) to 57% (2013) among adolescent girls and from 21 percent (2012) to 35% (2013) among adolescent boys. California’s rates for one or more doses of any HPV vaccine were 68% percent in 2013 for adolescent girls and 51% for adolescent boys, higher than the national average. Approximately one third of parents of girls and over half of parents of boys reported that their child’s clinician had not recommended that their child receive an HPV vaccination.

**Purpose:** The purpose of this biennial review is to review updates to the ACIP recommendations for influenza, Tdap, and HPV vaccines since the article was published.

**Data Criteria and Findings:**

1. *Influenza vaccine:* During both the 2014-15 and 2015-16 influenza seasons, ACIP recommended the use of live attenuated influenza vaccine (LAIV) for healthy children aged two through eight years without contraindications or precautions to the vaccine. However, this recommendation was reversed for the 2016-17 season, in light of low effectiveness in the United States during the 2013–14 and 2015–16 seasons. ACIP now recommends only use of the flu shot (inactivated influenza vaccine or IIV) and the recombinant influenza vaccine (RIV) during 2016-17.
2. **Tdap vaccine:** Postpartum Tdap vaccination and cocooning are no longer considered optimal strategies to prevent pertussis in infants. Recent studies examining structural birth defects in babies born to over 300,000 women receiving Tdap vaccination from 27 to 36 weeks gestation between 2010 and 2013 in California and other states found no association between microcephaly or other birth defects and receipt of Tdap. An additional study of 29,000 pregnancies found no association between Tdap vaccination within the past 2 to 5 years and adverse birth outcomes.

3. **HPV vaccine:** At their October 2016 meeting, ACIP unanimously voted to update recommendations for HPV vaccine. Two doses of HPV vaccine are now recommended for girls and boys ages 9 through 14 years, with dose 2 administered 6-12 months after the first dose (5 months minimum interval). Patients age 15 years or older or younger patients with immunocompromising conditions are recommended to complete a 3-dose schedule.

- **Analysis:** On June 30, 2015, California Senate Bill 277 (Pan, 2015) was signed into law, changing the immunization requirements for children entering child care or school in California starting January 1, 2016. Parents or guardians of students in any school or child care facility, whether public or private, will no longer be allowed to submit a personal beliefs exemption to a currently-required vaccine. California has a Tdap requirement for 7th grade entry. Providers should use this opportunity to co-administer HPV and meningococcal vaccines. Missed opportunities for HPV vaccination are very common. If providers would administer HPV vaccine when they give other recommended vaccines, coverage for the first dose could be greater than 90%.

- **Limitations:** None.

- **Research/Policy Recommendations:**

  1. Continue to educate patients and providers about pertussis, in particular among pregnant women and anyone who anticipates having close contact with an infant aged < 12 months.
  2. Continue to work with CDPH to promote that all ACIP-recommended adult immunizations are now available as a Medi-Cal pharmacy benefit.
  3. Continue to work with CDPH on the annual summaries of immunization guidelines, products, and/or research, in order to ensure the highest
priority information gets promoted through as many channels as possible.

4. Develop targeted DUR educational outreach to providers and pharmacies, as needed, to promote vaccination according to CDC guidelines.

5. Closely monitor surveillance reports for vaccine-preventable diseases through the CDPH website.

- **Clinical Recommendations:**
  1. All prescribers and pharmacies should review immunization status and other evidence of immunity to vaccine-preventable diseases for all patients.
  2. All health care providers should routinely encourage flu vaccine for all patients 6 months of age and older.
  3. All health care providers should feel comfortable addressing myths about vaccines and vaccine-preventable diseases.
  4. Improve practice patterns to use every opportunity to recommend HPV vaccines, specifically initiate the first dose with the required Tdap booster, which is required for entry into 7th grade in California.
  5. Providers should use the presumptive approach to improve HPV vaccination initiation rates for preteens ages 11-12 years. Research studies have found that announcements normalize HPV vaccination for both providers and parents, making providers more likely to raise the topic and parents more likely to consent to vaccination.
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 first quarter of 2017 (2017 Q1). 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 comparison to the prior quarter (2016 Q4), in 2017 Q1 there was an increase in overall drug claims (increased by 7%), DUR drug claims (increased by 2%), and total DUR alerts (increased by less than 1%). However, in comparison to the prior-year quarter (2016 Q1), overall drug claims decreased by 8%, DUR drug claims decreased by 15%, and total DUR alerts decreased by 10%.

A comparison between 2017 Q1 and 2016 Q4 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 2017 Q1 to the prior-year quarter showed an 11% decrease in total utilizing beneficiaries and a 15% decrease in total paid claims (Table 3). However, when overall utilization from 2017 Q1 was compared to the prior quarter there was an increase in total utilizing beneficiaries and total paid claims (both increased by 2%).

In 2017 Q1, all age groups posted across-the-board decreases in total utilizing beneficiaries and total paid claims in comparison to the prior-year quarter (Table 4). In comparison to the prior quarter, only the 65 years and older age group posted decreases in total utilizing beneficiaries (decreased by 4%) and total paid claims (decreased by 5%).

As shown in Table 5, the following two 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 ANTAGNST and ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED. Both categories contain only carved-out drugs.

In Table 6, QUETIAPINE FUMARATE and OLANZAPINE posted across-the-board increases in the percentage of utilizing beneficiaries with a paid claim and total paid claims from both the prior quarter and prior-year quarter (both are carved-out drugs). The following six drugs posted across-the-board decreases in the percentage of utilizing beneficiaries with a paid claim and total paid claims from both the prior quarter and prior-year quarter: ASPIRIN, DOCUSATE SODIUM, FOLIC ACID, HYDROCODONE/ACETAMINOPHEN, ACETAMINOPHEN and CEPHALEXIN.
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.

Table 1.1: Summary of Alert Transactions

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Claims</td>
<td>8,553,712</td>
<td>7,965,586</td>
<td>7.4%</td>
<td>9,320,333</td>
<td>-8.2%</td>
</tr>
<tr>
<td>DUR Drug Claims</td>
<td>4,052,003</td>
<td>3,973,976</td>
<td>2.0%</td>
<td>4,764,062</td>
<td>-14.9%</td>
</tr>
<tr>
<td>Total Alerts</td>
<td>959,197</td>
<td>958,615</td>
<td>0.1%</td>
<td>1,068,799</td>
<td>-10.3%</td>
</tr>
<tr>
<td>Total Alert Overrides</td>
<td>572,898</td>
<td>565,900</td>
<td>1.2%</td>
<td>626,134</td>
<td>-8.5%</td>
</tr>
<tr>
<td>Total Alert Cancels</td>
<td>134</td>
<td>163</td>
<td>-17.8%</td>
<td>281</td>
<td>-52.3%</td>
</tr>
</tbody>
</table>

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.

Table 1.2: Summary of Alert Transactions by Therapeutic Problem Type – 2017 Q1

<table>
<thead>
<tr>
<th>Therapeutic Problem Type</th>
<th>Total Alerts</th>
<th>Total Alert Overrides</th>
<th>% Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>% Alert Cancels</th>
<th>Total Alerts Not Adjudicated</th>
<th>% Alerts Not Adjudicated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Refill (ER)</td>
<td>295,777</td>
<td>96,327</td>
<td>32.6%</td>
<td>72</td>
<td>0.0%</td>
<td>199,378</td>
<td>67.4%</td>
</tr>
<tr>
<td>Ingredient Duplication (ID)</td>
<td>216,684</td>
<td>153,227</td>
<td>70.7%</td>
<td>17</td>
<td>0.0%</td>
<td>63,440</td>
<td>29.3%</td>
</tr>
<tr>
<td>Therapeutic Duplication (TD)</td>
<td>182,588</td>
<td>133,063</td>
<td>72.9%</td>
<td>19</td>
<td>0.0%</td>
<td>49,506</td>
<td>27.1%</td>
</tr>
<tr>
<td>Late Refill (LR)</td>
<td>118,777</td>
<td>91,041</td>
<td>76.6%</td>
<td>10</td>
<td>0.0%</td>
<td>27,726</td>
<td>23.3%</td>
</tr>
<tr>
<td>Total High Dose (HD)</td>
<td>51,809</td>
<td>31,551</td>
<td>60.9%</td>
<td>8</td>
<td>0.0%</td>
<td>20,250</td>
<td>39.1%</td>
</tr>
<tr>
<td>Additive Toxicity (AT)</td>
<td>34,318</td>
<td>27,214</td>
<td>79.3%</td>
<td>2</td>
<td>0.0%</td>
<td>7,102</td>
<td>20.7%</td>
</tr>
<tr>
<td>Total Low Dose (LD)</td>
<td>24,976</td>
<td>16,245</td>
<td>65.0%</td>
<td>2</td>
<td>0.0%</td>
<td>8,729</td>
<td>34.9%</td>
</tr>
<tr>
<td>Drug-Pregnancy (PG)</td>
<td>21,825</td>
<td>15,003</td>
<td>68.7%</td>
<td>2</td>
<td>0.0%</td>
<td>6,820</td>
<td>31.2%</td>
</tr>
<tr>
<td>Drug-Drug (DD)</td>
<td>9,688</td>
<td>7,214</td>
<td>74.5%</td>
<td>0</td>
<td>0.0%</td>
<td>2,474</td>
<td>25.5%</td>
</tr>
<tr>
<td>Drug-Disease (MC)</td>
<td>2,476</td>
<td>1,826</td>
<td>73.7%</td>
<td>0</td>
<td>0.0%</td>
<td>650</td>
<td>26.3%</td>
</tr>
<tr>
<td>Drug-Allergy (DA)</td>
<td>207</td>
<td>137</td>
<td>66.2%</td>
<td>0</td>
<td>0.0%</td>
<td>70</td>
<td>33.8%</td>
</tr>
<tr>
<td>Drug-Age (PA)</td>
<td>72</td>
<td>50</td>
<td>69.4%</td>
<td>0</td>
<td>0.0%</td>
<td>22</td>
<td>30.6%</td>
</tr>
</tbody>
</table>
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.

Table 2.1: Top 10 Drugs by Therapeutic Problem Type – Drug-Allergy (DA) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PHENYTOIN SODIUM EXTENDED</td>
<td>107</td>
<td>107</td>
<td>0</td>
<td>2,314</td>
<td>4.6%</td>
</tr>
<tr>
<td>2</td>
<td>PHENYTOIN</td>
<td>48</td>
<td>48</td>
<td>0</td>
<td>877</td>
<td>5.5%</td>
</tr>
<tr>
<td>3</td>
<td>AMOXICILLIN</td>
<td>12</td>
<td>12</td>
<td>0</td>
<td>49,507</td>
<td>0.0%</td>
</tr>
<tr>
<td>4</td>
<td>OXYCODONE HCL/ACETAMINOPHEN</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>6,568</td>
<td>0.1%</td>
</tr>
<tr>
<td>5</td>
<td>IBUPROFEN</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td>93,492</td>
<td>0.0%</td>
</tr>
<tr>
<td>6</td>
<td>SULFAMETHOXAZOLE/TRIMETHOPRIM</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>18,207</td>
<td>0.0%</td>
</tr>
<tr>
<td>7</td>
<td>OXYCODONE HCL</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>4,194</td>
<td>0.0%</td>
</tr>
<tr>
<td>8</td>
<td>AMOXICILLIN/POTASSIUM CLAV</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>13,128</td>
<td>0.0%</td>
</tr>
<tr>
<td>9</td>
<td>SOMATROPIN</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2,064</td>
<td>0.0%</td>
</tr>
<tr>
<td>10</td>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>37,353</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Table 2.2: Top 10 Drugs by Therapeutic Problem Type – Drug-Pregnancy (PG) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBUPROFEN</td>
<td>12,944</td>
<td>12,942</td>
<td>2</td>
<td>93,492</td>
<td>13.8%</td>
</tr>
<tr>
<td>2</td>
<td>NORETHINDRONE</td>
<td>2,394</td>
<td>2,394</td>
<td>0</td>
<td>7,922</td>
<td>30.2%</td>
</tr>
<tr>
<td>3</td>
<td>SULFAMETHOXAZOLE/TRIMETHOPRIM</td>
<td>436</td>
<td>436</td>
<td>0</td>
<td>18,207</td>
<td>2.4%</td>
</tr>
<tr>
<td>4</td>
<td>METHYLERGONOVINE MALEATE</td>
<td>362</td>
<td>362</td>
<td>0</td>
<td>223</td>
<td>162.3%</td>
</tr>
<tr>
<td>5</td>
<td>MISOPROSTOL</td>
<td>290</td>
<td>290</td>
<td>0</td>
<td>722</td>
<td>40.2%</td>
</tr>
<tr>
<td>6</td>
<td>NAPROXEN</td>
<td>256</td>
<td>256</td>
<td>0</td>
<td>12,773</td>
<td>2.0%</td>
</tr>
<tr>
<td>7</td>
<td>DOXYCYCLINE HYCLATE</td>
<td>250</td>
<td>250</td>
<td>0</td>
<td>5,535</td>
<td>4.5%</td>
</tr>
<tr>
<td>8</td>
<td>LORAZEPAM</td>
<td>151</td>
<td>151</td>
<td>0</td>
<td>10,490</td>
<td>1.4%</td>
</tr>
<tr>
<td>9</td>
<td>LINSINOPRIL</td>
<td>107</td>
<td>107</td>
<td>0</td>
<td>33,513</td>
<td>0.3%</td>
</tr>
<tr>
<td>10</td>
<td>METHIMAZOLE</td>
<td>94</td>
<td>94</td>
<td>0</td>
<td>1,459</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

Table 2.3: Top 10 Drugs by Therapeutic Problem Type – Drug-Disease (MC) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>POTASSIUM CHLORIDE</td>
<td>493</td>
<td>493</td>
<td>0</td>
<td>3,567</td>
<td>13.8%</td>
</tr>
<tr>
<td>2</td>
<td>HALOPERIDOL</td>
<td>392</td>
<td>392</td>
<td>0</td>
<td>21,070</td>
<td>1.9%</td>
</tr>
<tr>
<td>3</td>
<td>METFORMIN HCL</td>
<td>346</td>
<td>345</td>
<td>1</td>
<td>41,431</td>
<td>0.8%</td>
</tr>
<tr>
<td>4</td>
<td>HALOPERIDOL DECANOATE</td>
<td>72</td>
<td>72</td>
<td>0</td>
<td>3,801</td>
<td>1.9%</td>
</tr>
<tr>
<td>5</td>
<td>CARBAMAZEPINE</td>
<td>71</td>
<td>71</td>
<td>0</td>
<td>3,484</td>
<td>2.0%</td>
</tr>
<tr>
<td>6</td>
<td>METOPROLOL SUCCINATE</td>
<td>62</td>
<td>62</td>
<td>0</td>
<td>5,317</td>
<td>1.2%</td>
</tr>
<tr>
<td>7</td>
<td>METOPROLOL TARTRATE</td>
<td>49</td>
<td>49</td>
<td>0</td>
<td>8,106</td>
<td>0.6%</td>
</tr>
<tr>
<td>8</td>
<td>PROPRANOLOL HCL</td>
<td>45</td>
<td>45</td>
<td>0</td>
<td>4,314</td>
<td>1.0%</td>
</tr>
<tr>
<td>9</td>
<td>ATENOLOL</td>
<td>44</td>
<td>44</td>
<td>0</td>
<td>6,504</td>
<td>0.7%</td>
</tr>
<tr>
<td>10</td>
<td>LEVONORGESTREL-ETHIN ESTRADIOL</td>
<td>39</td>
<td>39</td>
<td>0</td>
<td>19,316</td>
<td>0.2%</td>
</tr>
</tbody>
</table>
### Table 2.4: Top 10 Drugs by Therapeutic Problem Type – Drug-Drug Interaction (DD) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ELVITEG/COBI/EMTRIC/TENOFO ALA</td>
<td>689</td>
<td>689</td>
<td>0</td>
<td>10,908</td>
<td>6.3%</td>
</tr>
<tr>
<td>2</td>
<td>GEMFIBROZIL</td>
<td>551</td>
<td>551</td>
<td>0</td>
<td>2,791</td>
<td>19.7%</td>
</tr>
<tr>
<td>3</td>
<td>SIMVASTATIN</td>
<td>408</td>
<td>408</td>
<td>0</td>
<td>12,683</td>
<td>3.2%</td>
</tr>
<tr>
<td>4</td>
<td>DARUNAVIR ETHANOLATE</td>
<td>395</td>
<td>395</td>
<td>0</td>
<td>5,909</td>
<td>6.7%</td>
</tr>
<tr>
<td>5</td>
<td>METOCLOPRAMIDE HCL</td>
<td>341</td>
<td>341</td>
<td>0</td>
<td>25,718</td>
<td>1.3%</td>
</tr>
<tr>
<td>6</td>
<td>ATORVASTATIN CALCII</td>
<td>331</td>
<td>331</td>
<td>0</td>
<td>21,899</td>
<td>1.2%</td>
</tr>
<tr>
<td>7</td>
<td>AMLODIPINE BESYLATE</td>
<td>257</td>
<td>257</td>
<td>0</td>
<td>19,159</td>
<td>3.9%</td>
</tr>
<tr>
<td>8</td>
<td>DARUNAVIR/Cobicistat</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>4,899</td>
<td>3.9%</td>
</tr>
<tr>
<td>9</td>
<td>ZIPRASIDONE HCL</td>
<td>175</td>
<td>175</td>
<td>0</td>
<td>19,159</td>
<td>0.9%</td>
</tr>
<tr>
<td>10</td>
<td>ETRAVIRINE</td>
<td>171</td>
<td>171</td>
<td>0</td>
<td>1,253</td>
<td>13.6%</td>
</tr>
</tbody>
</table>

### Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QUETIAPINE FUMARATE</td>
<td>24,554</td>
<td>24,553</td>
<td>1</td>
<td>139,650</td>
<td>17.6%</td>
</tr>
<tr>
<td>2</td>
<td>OLANZAPINE</td>
<td>16,106</td>
<td>16,106</td>
<td>0</td>
<td>74,870</td>
<td>21.5%</td>
</tr>
<tr>
<td>3</td>
<td>RISPERIDONE</td>
<td>14,839</td>
<td>14,838</td>
<td>1</td>
<td>85,841</td>
<td>17.3%</td>
</tr>
<tr>
<td>4</td>
<td>LURASIDONE HCL</td>
<td>9,627</td>
<td>9,626</td>
<td>1</td>
<td>37,278</td>
<td>25.8%</td>
</tr>
<tr>
<td>5</td>
<td>CLOZAPINE</td>
<td>6,279</td>
<td>6,279</td>
<td>0</td>
<td>19,218</td>
<td>32.7%</td>
</tr>
<tr>
<td>6</td>
<td>PALIPERIDONE PALMITATE</td>
<td>5,881</td>
<td>5,880</td>
<td>1</td>
<td>15,653</td>
<td>37.6%</td>
</tr>
<tr>
<td>7</td>
<td>ZIPRASIDONE HCL</td>
<td>4,867</td>
<td>4,867</td>
<td>0</td>
<td>19,159</td>
<td>25.4%</td>
</tr>
<tr>
<td>8</td>
<td>TRAZODONE HCL</td>
<td>4,632</td>
<td>4,631</td>
<td>0</td>
<td>10,648</td>
<td>43.5%</td>
</tr>
<tr>
<td>9</td>
<td>ALBUTEROL SULFATE</td>
<td>4,151</td>
<td>4,151</td>
<td>0</td>
<td>57,453</td>
<td>7.2%</td>
</tr>
<tr>
<td>10</td>
<td>PREDNISONE</td>
<td>3,861</td>
<td>3,861</td>
<td>0</td>
<td>19,568</td>
<td>19.7%</td>
</tr>
</tbody>
</table>

### Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QUETIAPINE FUMARATE</td>
<td>9,684</td>
<td>9,681</td>
<td>3</td>
<td>139,650</td>
<td>6.9%</td>
</tr>
<tr>
<td>2</td>
<td>ARIPIPRAZOLE</td>
<td>7,467</td>
<td>7,463</td>
<td>4</td>
<td>101,553</td>
<td>7.3%</td>
</tr>
<tr>
<td>3</td>
<td>RISPERIDONE</td>
<td>5,169</td>
<td>5,166</td>
<td>3</td>
<td>85,841</td>
<td>6.0%</td>
</tr>
<tr>
<td>4</td>
<td>OLANZAPINE</td>
<td>4,721</td>
<td>4,719</td>
<td>2</td>
<td>74,870</td>
<td>6.3%</td>
</tr>
<tr>
<td>5</td>
<td>BENZTROPINE MESYLATE</td>
<td>4,174</td>
<td>4,174</td>
<td>0</td>
<td>56,217</td>
<td>7.4%</td>
</tr>
<tr>
<td>6</td>
<td>LITHIUM CARBONATE</td>
<td>2,432</td>
<td>2,431</td>
<td>1</td>
<td>30,219</td>
<td>8.0%</td>
</tr>
<tr>
<td>7</td>
<td>LURASIDONE HCL</td>
<td>2,166</td>
<td>2,166</td>
<td>0</td>
<td>37,278</td>
<td>5.8%</td>
</tr>
<tr>
<td>8</td>
<td>ASPIRIN</td>
<td>2,078</td>
<td>2,078</td>
<td>0</td>
<td>65,945</td>
<td>3.2%</td>
</tr>
<tr>
<td>9</td>
<td>METFORMIN HCL</td>
<td>1,940</td>
<td>1,938</td>
<td>2</td>
<td>41,431</td>
<td>4.7%</td>
</tr>
<tr>
<td>10</td>
<td>HALOPERIDOL</td>
<td>1,746</td>
<td>1,745</td>
<td>1</td>
<td>21,070</td>
<td>8.3%</td>
</tr>
</tbody>
</table>
### Table 2.7: Top 10 Drugs by Therapeutic Problem Type – Underutilization (LR) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ARIPIPRAZOLE</td>
<td>17,896</td>
<td>17,896</td>
<td>0</td>
<td>101,553</td>
<td>17.6%</td>
</tr>
<tr>
<td>2</td>
<td>QUETIAPINE FUMARATE</td>
<td>16,766</td>
<td>16,764</td>
<td>2</td>
<td>139,650</td>
<td>12.0%</td>
</tr>
<tr>
<td>3</td>
<td>RISPERIDONE</td>
<td>9,919</td>
<td>9,917</td>
<td>2</td>
<td>85,841</td>
<td>11.6%</td>
</tr>
<tr>
<td>4</td>
<td>OLANZAPINE</td>
<td>7,798</td>
<td>7,798</td>
<td>0</td>
<td>74,870</td>
<td>10.4%</td>
</tr>
<tr>
<td>5</td>
<td>BENZTROPINE MESYLATE</td>
<td>7,126</td>
<td>7,126</td>
<td>0</td>
<td>56,217</td>
<td>12.7%</td>
</tr>
<tr>
<td>6</td>
<td>LURASIDONE HCL</td>
<td>5,241</td>
<td>5,241</td>
<td>0</td>
<td>37,278</td>
<td>14.1%</td>
</tr>
<tr>
<td>7</td>
<td>LITHIUM CARBONATE</td>
<td>4,321</td>
<td>4,321</td>
<td>0</td>
<td>30,219</td>
<td>14.3%</td>
</tr>
<tr>
<td>8</td>
<td>LEVOTHYROXINE SODIUM</td>
<td>3,076</td>
<td>3,076</td>
<td>0</td>
<td>26,218</td>
<td>11.7%</td>
</tr>
<tr>
<td>9</td>
<td>ATORVASTATIN CALCIUM</td>
<td>2,606</td>
<td>2,606</td>
<td>0</td>
<td>25,718</td>
<td>10.4%</td>
</tr>
<tr>
<td>10</td>
<td>GABAPENTIN</td>
<td>2,452</td>
<td>2,452</td>
<td>0</td>
<td>22,210</td>
<td>11.0%</td>
</tr>
</tbody>
</table>

### Table 2.8: Top 10 Drugs by Therapeutic Problem Type – Additive Toxicity (AT) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ARIPIPRAZOLE</td>
<td>1,692</td>
<td>1,692</td>
<td>0</td>
<td>101,553</td>
<td>1.7%</td>
</tr>
<tr>
<td>2</td>
<td>QUETIAPINE FUMARATE</td>
<td>1,555</td>
<td>1,555</td>
<td>0</td>
<td>139,650</td>
<td>1.1%</td>
</tr>
<tr>
<td>3</td>
<td>LITHIUM CARBONATE</td>
<td>1,429</td>
<td>1,429</td>
<td>0</td>
<td>30,219</td>
<td>4.7%</td>
</tr>
<tr>
<td>4</td>
<td>CLONAZEPAM</td>
<td>1,184</td>
<td>1,184</td>
<td>0</td>
<td>7,921</td>
<td>14.9%</td>
</tr>
<tr>
<td>5</td>
<td>HALOPERIDOL</td>
<td>1,014</td>
<td>1,014</td>
<td>0</td>
<td>21,070</td>
<td>4.8%</td>
</tr>
<tr>
<td>6</td>
<td>OLANZAPINE</td>
<td>864</td>
<td>864</td>
<td>0</td>
<td>7,921</td>
<td>1.2%</td>
</tr>
<tr>
<td>7</td>
<td>ZOLPIDEM TARTRATE</td>
<td>643</td>
<td>643</td>
<td>0</td>
<td>4,238</td>
<td>15.2%</td>
</tr>
<tr>
<td>8</td>
<td>TRAZODONE HCL</td>
<td>574</td>
<td>574</td>
<td>0</td>
<td>10,648</td>
<td>5.4%</td>
</tr>
<tr>
<td>9</td>
<td>RISPERIDONE</td>
<td>569</td>
<td>569</td>
<td>0</td>
<td>85,841</td>
<td>0.7%</td>
</tr>
<tr>
<td>10</td>
<td>BUSPIRONE HCL</td>
<td>441</td>
<td>441</td>
<td>0</td>
<td>3,341</td>
<td>13.2%</td>
</tr>
</tbody>
</table>

### Table 2.9: Top 10 Drugs by Therapeutic Problem Type – Ingredient Duplication (ID) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QUETIAPINE FUMARATE</td>
<td>30,678</td>
<td>30,677</td>
<td>1</td>
<td>139,650</td>
<td>22.0%</td>
</tr>
<tr>
<td>2</td>
<td>OLANZAPINE</td>
<td>14,819</td>
<td>14,817</td>
<td>2</td>
<td>74,870</td>
<td>19.8%</td>
</tr>
<tr>
<td>3</td>
<td>ARIPIPRAZOLE</td>
<td>13,106</td>
<td>13,103</td>
<td>3</td>
<td>101,553</td>
<td>12.9%</td>
</tr>
<tr>
<td>4</td>
<td>RISPERIDONE</td>
<td>11,549</td>
<td>11,547</td>
<td>2</td>
<td>85,841</td>
<td>13.5%</td>
</tr>
<tr>
<td>5</td>
<td>CLOzapine</td>
<td>6,847</td>
<td>6,847</td>
<td>0</td>
<td>19,218</td>
<td>35.6%</td>
</tr>
<tr>
<td>6</td>
<td>ALBUTEROL SULFATE</td>
<td>6,459</td>
<td>6,459</td>
<td>0</td>
<td>57,453</td>
<td>11.2%</td>
</tr>
<tr>
<td>7</td>
<td>LURASIDONE HCL</td>
<td>5,519</td>
<td>5,517</td>
<td>2</td>
<td>37,278</td>
<td>14.8%</td>
</tr>
<tr>
<td>8</td>
<td>ZIPRASIDONE HCL</td>
<td>3,762</td>
<td>3,762</td>
<td>0</td>
<td>19,159</td>
<td>19.6%</td>
</tr>
<tr>
<td>9</td>
<td>HALOPERIDOL</td>
<td>3,567</td>
<td>3,567</td>
<td>0</td>
<td>21,070</td>
<td>16.9%</td>
</tr>
<tr>
<td>10</td>
<td>LEVOTHYROXINE SODIUM</td>
<td>2,813</td>
<td>2,813</td>
<td>0</td>
<td>26,218</td>
<td>10.7%</td>
</tr>
</tbody>
</table>
### Table 2.10: Top 10 Drugs by Therapeutic Problem Type – Drug-Age (PA) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AMITRIPTYLINE HCL</td>
<td>29</td>
<td>29</td>
<td>0</td>
<td>3,536</td>
<td>0.8%</td>
</tr>
<tr>
<td>2</td>
<td>PALIVIZUMAB</td>
<td>22</td>
<td>22</td>
<td>0</td>
<td>2,449</td>
<td>0.9%</td>
</tr>
<tr>
<td>3</td>
<td>DOXEPIN HCL</td>
<td>14</td>
<td>14</td>
<td>0</td>
<td>381</td>
<td>3.7%</td>
</tr>
<tr>
<td>4</td>
<td>AMOXICILLIN</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>49,507</td>
<td>0.0%</td>
</tr>
<tr>
<td>5</td>
<td>FERROUS SULFATE</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>42,643</td>
<td>0.0%</td>
</tr>
<tr>
<td>6</td>
<td>TACROLIMUS</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>4,352</td>
<td>0.1%</td>
</tr>
<tr>
<td>7</td>
<td>ATOVACQUONE</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>308</td>
<td>0.6%</td>
</tr>
<tr>
<td>8</td>
<td>BUDESONIDE</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>4,736</td>
<td>0.0%</td>
</tr>
<tr>
<td>9</td>
<td>ACETAMINOPHEN</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>26,229</td>
<td>0.0%</td>
</tr>
<tr>
<td>10</td>
<td>QUETIAPINE FUMARATE</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>139,650</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

### Table 2.11: Top 10 Drugs by Therapeutic Problem Type – High Dose (HD) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OLANZAPINE</td>
<td>8,130</td>
<td>8,130</td>
<td>0</td>
<td>74,870</td>
<td>10.9%</td>
</tr>
<tr>
<td>2</td>
<td>RISPERIDONE</td>
<td>2,545</td>
<td>2,544</td>
<td>1</td>
<td>85,841</td>
<td>3.0%</td>
</tr>
<tr>
<td>3</td>
<td>QUETIAPINE FUMARATE</td>
<td>2,214</td>
<td>2,214</td>
<td>0</td>
<td>139,650</td>
<td>1.6%</td>
</tr>
<tr>
<td>4</td>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>1,959</td>
<td>1,959</td>
<td>0</td>
<td>37,353</td>
<td>5.2%</td>
</tr>
<tr>
<td>5</td>
<td>AMOXICILLIN</td>
<td>1,471</td>
<td>1,471</td>
<td>0</td>
<td>49,507</td>
<td>3.0%</td>
</tr>
<tr>
<td>6</td>
<td>IBUPROFEN</td>
<td>1,348</td>
<td>1,348</td>
<td>0</td>
<td>93,492</td>
<td>1.4%</td>
</tr>
<tr>
<td>7</td>
<td>GABAPENTIN</td>
<td>1,296</td>
<td>1,295</td>
<td>1</td>
<td>22,210</td>
<td>5.8%</td>
</tr>
<tr>
<td>8</td>
<td>AMOXICILLIN/POTASSIUM CLAV</td>
<td>1,067</td>
<td>1,067</td>
<td>0</td>
<td>13,128</td>
<td>8.1%</td>
</tr>
<tr>
<td>9</td>
<td>ARIPIPRAZOLE</td>
<td>1,020</td>
<td>1,020</td>
<td>0</td>
<td>101,553</td>
<td>1.0%</td>
</tr>
<tr>
<td>10</td>
<td>ALBUTEROL SULFATE</td>
<td>756</td>
<td>753</td>
<td>3</td>
<td>57,453</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

### Table 2.12: Top 10 Drugs by Therapeutic Problem Type – Low Dose (LD) – 2017 Q1

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug Generic Name/Ingredient Name</th>
<th>Total Adjudicated Alerts</th>
<th>Total Alert Overrides</th>
<th>Total Alert Cancels</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims with Alert Overrides</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LITHIUM CARBONATE</td>
<td>4,610</td>
<td>4,609</td>
<td>1</td>
<td>30,219</td>
<td>15.3%</td>
</tr>
<tr>
<td>2</td>
<td>GABAPENTIN</td>
<td>1,677</td>
<td>1,677</td>
<td>0</td>
<td>22,210</td>
<td>7.6%</td>
</tr>
<tr>
<td>3</td>
<td>AZITHROMYCIN</td>
<td>924</td>
<td>924</td>
<td>0</td>
<td>32,722</td>
<td>2.8%</td>
</tr>
<tr>
<td>4</td>
<td>ALBUTEROL SULFATE</td>
<td>859</td>
<td>859</td>
<td>0</td>
<td>57,453</td>
<td>1.5%</td>
</tr>
<tr>
<td>5</td>
<td>DIVALPROEX SODIUM</td>
<td>736</td>
<td>736</td>
<td>0</td>
<td>11,882</td>
<td>6.2%</td>
</tr>
<tr>
<td>6</td>
<td>AMOXICILLIN/POTASSIUM CLAV</td>
<td>662</td>
<td>662</td>
<td>0</td>
<td>13,128</td>
<td>5.0%</td>
</tr>
<tr>
<td>7</td>
<td>AMOXICILLIN</td>
<td>632</td>
<td>632</td>
<td>0</td>
<td>49,507</td>
<td>1.3%</td>
</tr>
<tr>
<td>8</td>
<td>ERYTHROMYCIN ETHYLSUCCINATE</td>
<td>547</td>
<td>547</td>
<td>0</td>
<td>1,873</td>
<td>29.2%</td>
</tr>
<tr>
<td>9</td>
<td>CLONIDINE HCL</td>
<td>351</td>
<td>351</td>
<td>0</td>
<td>8,845</td>
<td>4.0%</td>
</tr>
<tr>
<td>10</td>
<td>SULFAMETHOXAZOLE/TRIMETHOPRIM</td>
<td>312</td>
<td>312</td>
<td>0</td>
<td>18,207</td>
<td>1.7%</td>
</tr>
</tbody>
</table>
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.

Table 3: Pharmacy Utilization Measures for the Medi-Cal FFS Population

<table>
<thead>
<tr>
<th>Category</th>
<th>Current Quarter 2017 Q1</th>
<th>Prior Quarter 2016 Q4</th>
<th>Prior-Year Quarter 2016 Q1</th>
<th>% Change from Prior Quarter</th>
<th>% Change from Prior-Year Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Eligible FFS Beneficiaries</td>
<td>2,361,077</td>
<td>2,408,495</td>
<td>2,826,539</td>
<td>-2.0%</td>
<td>-16.5%</td>
</tr>
<tr>
<td>Total Utilizing FFS Beneficiaries</td>
<td>767,587</td>
<td>751,505</td>
<td>865,726</td>
<td>2.1%</td>
<td>-11.3%</td>
</tr>
<tr>
<td>Total Paid Rx Claims</td>
<td>2,569,845</td>
<td>2,526,060</td>
<td>3,021,024</td>
<td>1.7%</td>
<td>-14.9%</td>
</tr>
<tr>
<td>Average Paid Rx Claims per Eligible FFS Beneficiary</td>
<td>1.09</td>
<td>1.05</td>
<td>1.07</td>
<td>3.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Average Paid Rx Claims per Utilizing FFS Beneficiary</td>
<td>3.35</td>
<td>3.36</td>
<td>3.49</td>
<td>-0.4%</td>
<td>-4.1%</td>
</tr>
<tr>
<td>Total Reimbursement Paid ($) to Pharmacies</td>
<td>$585,531,625</td>
<td>$567,660,492</td>
<td>$748,793,485</td>
<td>3.1%</td>
<td>-21.8%</td>
</tr>
<tr>
<td>Average Reimbursement Paid ($) per Eligible FFS Beneficiary</td>
<td>$247.99</td>
<td>$235.69</td>
<td>$264.92</td>
<td>5.2%</td>
<td>-6.4%</td>
</tr>
<tr>
<td>Average Reimbursement Paid ($) per Utilizing FFS Beneficiary</td>
<td>$762.82</td>
<td>$755.36</td>
<td>$864.93</td>
<td>1.0%</td>
<td>-11.8%</td>
</tr>
<tr>
<td>Average Reimbursement Paid ($) per Paid Rx Claim</td>
<td>$227.85</td>
<td>$224.72</td>
<td>$247.86</td>
<td>1.4%</td>
<td>-8.1%</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Age Group (years)</th>
<th>Current Quarter 2017 Q1 Total Paid Claims</th>
<th>% Change Total Paid Claims from Prior Year Quarter</th>
<th>% Change Total Paid Claims from Prior-Year Quarter</th>
<th>Current Quarter 2017 Q1 Total Utilizing Beneficiaries</th>
<th>% Change Total Utilizing Beneficiaries from Prior Quarter</th>
<th>% Change Total Utilizing Beneficiaries from Prior-Year Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 12</td>
<td>255,592</td>
<td>6.7%</td>
<td>-24.3%</td>
<td>106,211</td>
<td>5.0%</td>
<td>-21.8%</td>
</tr>
<tr>
<td>13 – 18</td>
<td>122,781</td>
<td>1.9%</td>
<td>-18.5%</td>
<td>38,191</td>
<td>2.7%</td>
<td>-18.5%</td>
</tr>
<tr>
<td>19 – 39</td>
<td>780,769</td>
<td>2.6%</td>
<td>-12.7%</td>
<td>251,257</td>
<td>2.9%</td>
<td>-10.2%</td>
</tr>
<tr>
<td>40 – 64</td>
<td>1,156,595</td>
<td>1.3%</td>
<td>-12.1%</td>
<td>283,706</td>
<td>2.0%</td>
<td>-5.8%</td>
</tr>
<tr>
<td>65+</td>
<td>234,726</td>
<td>-5.1%</td>
<td>-22.1%</td>
<td>80,713</td>
<td>-4.2%</td>
<td>-13.8%</td>
</tr>
<tr>
<td>Total*</td>
<td>2,569,845</td>
<td>1.7%</td>
<td>-14.9%</td>
<td>767,587</td>
<td>2.1%</td>
<td>-11.3%</td>
</tr>
</tbody>
</table>

* 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.

Table 5: Top 20 Drug Therapeutic Categories by Percentage of Utilizing Beneficiaries with a Paid Claim

| Rank | Last Year Rank | Drug Therapeutic Category Description | Current Quarter 2017 Q1 Total Paid Claims | % Change Total Paid Claims from Prior Quarter | % Change Total Paid Claims from Prior-Year Quarter | Current Quarter 2017 Q1 Total UtilizingBeneficiaries | % Utilizing Beneficiaries with a Paid Claim | % Change Utilizing Beneficiaries with a Paid Claim from Prior Quarter | % Change Utilizing Beneficiaries with a Paid Claim from Prior-Year Quarter |
|------|----------------|--------------------------------------|------------------------------------------|--------------------------------------------|--------------------------------|
| 1    | 1              | ANTIPSYCHOTIC,ATYPICAL,DOPAMINE,5HT ANTAGNST | 403,155                                  | 1.4%                                       | 1.2%                                       | 138,820                                   | 18.1%                                     | 0.0%                                         | 2.4%                                         |
| 2    | 2              | NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS | 111,742                                  | 5.6%                                       | -22.9%                                    | 96,640                                   | 12.6%                                     | 0.4%                                         | -1.8%                                        |
| 3    | 3              | PENICILLINS                             | 66,921                                   | 18.9%                                      | -24.5%                                    | 60,724                                   | 7.9%                                      | 1.1%                                         | -1.3%                                        |
| 4    | 7              | ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED | 104,723                                  | 1.5%                                       | 0.9%                                      | 45,775                                   | 6.0%                                      | 0.0%                                         | 0.7%                                         |
| 5    | 6              | PLATELET AGGREGATION INHIBITORS         | 65,555                                   | -7.4%                                      | -13.8%                                    | 44,240                                   | 5.8%                                      | -0.4%                                        | 0.0%                                         |
| 6    | 4              | NARCOTIC ANALGESIC AND NON-SALICYLATE ANALGESIC | 54,229                                    | -4.6%                                      | -27.9%                                    | 43,171                                   | 5.6%                                      | -0.4%                                        | -1.2%                                        |
| 7    | 5              | BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING | 51,811                                    | 14.4%                                      | -22.9%                                    | 39,436                                   | 5.1%                                      | 0.7%                                         | -0.7%                                        |
| 8    | 9              | ANTIHISTAMINES - 2ND GENERATION         | 47,846                                   | 5.0%                                       | -16.4%                                    | 33,303                                   | 4.3%                                      | 0.4%                                         | -0.3%                                        |
| 9    | 11             | IRON REPLACEMENT                        | 41,517                                   | 0.8%                                       | -14.1%                                    | 32,221                                   | 4.2%                                      | 0.0%                                         | -0.1%                                        |
| 10   | 8              | LAXATIVES AND CATHARTICS               | 47,593                                   | -9.2%                                      | -20.8%                                    | 32,079                                   | 4.2%                                      | -0.4%                                        | -0.5%                                        |
| 11   | 12             | ANTICONVULSANTS                         | 77,879                                   | -1.6%                                      | -18.4%                                    | 30,788                                   | 4.0%                                      | 0.0%                                         | -0.2%                                        |
| 12   | 13             | ANTIHYPERTENSIVES, ACE INHIBITORS       | 43,689                                   | 0.9%                                       | -19.5%                                    | 29,176                                   | 3.8%                                      | 0.0%                                         | -0.2%                                        |
| 13   | 15             | ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS | 44,084                                  | 1.6%                                       | -14.2%                                    | 29,019                                   | 3.8%                                      | 0.1%                                         | 0.0%                                         |
| 14   | 10             | MACROLIDES                              | 29,282                                   | 24.1%                                      | -31.5%                                    | 26,852                                   | 3.5%                                      | 0.7%                                         | -1.0%                                        |
| 15   | 18             | ANTIHYPERGLYCEMIC, BIGUANIDE TYPE       | 39,324                                   | 2.8%                                       | -13.5%                                    | 26,459                                   | 3.4%                                      | 0.1%                                         | 0.0%                                         |
| 16   | 23             | ANTIPARKINSONISM DRUGS,ANTICHOLINERGIC | 61,342                                   | -1.3%                                      | -4.5%                                      | 24,516                                   | 3.2%                                      | -0.1%                                        | 0.2%                                         |
| 17   | 17             | PREGNATAL VITAMIN PREPARATIONS         | 27,219                                   | 4.9%                                       | -23.2%                                    | 24,162                                   | 3.1%                                      | 0.1%                                         | -0.5%                                        |
| 18   | 14             | ANALGESIC/ANTIPYRETICS, NON-SALICYLATE | 25,639                                   | 0.1%                                       | -28.1%                                    | 23,860                                   | 3.1%                                      | -0.1%                                        | -0.7%                                        |
| 19   | 16             | NON-NARC ANTITUSSIVE-1ST GEN ANTIHISTAMINE COMB. | 25,810                                  | 22.3%                                      | -27.5%                                    | 22,803                                   | 3.0%                                      | 0.5%                                         | -0.7%                                        |
| 20   | 21             | CEPHALOSPORINS - 1ST GENERATION         | 24,175                                   | -1.4%                                      | -18.8%                                    | 22,775                                   | 3.0%                                      | -0.1%                                        | -0.3%                                        |
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

<table>
<thead>
<tr>
<th>Rank</th>
<th>Last Year Rank</th>
<th>Drug Description</th>
<th>Current Quarter 2017 Q1 Total Paid Claims</th>
<th>% Change Total Paid Claims from Prior Quarter</th>
<th>% Change Total Paid Claims from Prior-Year Quarter</th>
<th>Current Quarter 2017 Q1 Total Utilizing Beneficiaries with a Paid Claim</th>
<th>% Change of Utilizing Beneficiaries with a Paid Claim from Prior Quarter</th>
<th>% Change of Utilizing Beneficiaries with a Paid Claim from Prior-Year Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>IBUPROFEN</td>
<td>92,964</td>
<td>6.8%</td>
<td>-23.3%</td>
<td>82,827</td>
<td>10.8%</td>
<td>0.5%</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>QUETIAPINE FUMARATE</td>
<td>139,486</td>
<td>2.1%</td>
<td>2.2%</td>
<td>54,466</td>
<td>7.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>AMOXICILLIN</td>
<td>48,932</td>
<td>19.7%</td>
<td>-25.3%</td>
<td>45,338</td>
<td>5.9%</td>
<td>0.9%</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>ARIPIPRAZOLE</td>
<td>101,313</td>
<td>1.1%</td>
<td>-1.4%</td>
<td>44,512</td>
<td>5.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>ASPIRIN</td>
<td>64,954</td>
<td>-9.3%</td>
<td>-16.2%</td>
<td>44,510</td>
<td>5.8%</td>
<td>-0.5%</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>ALBUTEROL SULFATE</td>
<td>53,945</td>
<td>14.6%</td>
<td>-23.5%</td>
<td>41,301</td>
<td>5.4%</td>
<td>0.7%</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>RISPERIDONE</td>
<td>85,140</td>
<td>0.6%</td>
<td>-4.9%</td>
<td>34,737</td>
<td>4.5%</td>
<td>0.0%</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>LORATADINE</td>
<td>47,345</td>
<td>5.1%</td>
<td>-16.3%</td>
<td>33,081</td>
<td>4.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>9</td>
<td>11</td>
<td>FERROUS SULFATE</td>
<td>41,479</td>
<td>2.3%</td>
<td>-12.0%</td>
<td>32,201</td>
<td>4.2%</td>
<td>0.1%</td>
</tr>
<tr>
<td>10</td>
<td>9</td>
<td>DOCUSATE SODIUM</td>
<td>44,789</td>
<td>-8.6%</td>
<td>-19.6%</td>
<td>30,799</td>
<td>4.0%</td>
<td>-0.4%</td>
</tr>
<tr>
<td>11</td>
<td>7</td>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>36,864</td>
<td>-5.6%</td>
<td>-27.1%</td>
<td>30,314</td>
<td>3.9%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>12</td>
<td>17</td>
<td>OLANZAPINE</td>
<td>74,760</td>
<td>2.7%</td>
<td>1.4%</td>
<td>28,923</td>
<td>3.8%</td>
<td>0.1%</td>
</tr>
<tr>
<td>13</td>
<td>15</td>
<td>METFORMIN HCL</td>
<td>39,324</td>
<td>3.0%</td>
<td>-13.4%</td>
<td>26,459</td>
<td>3.4%</td>
<td>0.1%</td>
</tr>
<tr>
<td>14</td>
<td>10</td>
<td>AZITHROMYCIN</td>
<td>26,869</td>
<td>26.3%</td>
<td>-32.2%</td>
<td>25,186</td>
<td>3.3%</td>
<td>0.7%</td>
</tr>
<tr>
<td>15</td>
<td>13</td>
<td>ACETAMINOPHEN</td>
<td>25,639</td>
<td>-0.2%</td>
<td>-28.3%</td>
<td>23,860</td>
<td>3.1%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>16</td>
<td>14</td>
<td>PROMETHAZINE/DEXTROMETHORPHAN</td>
<td>25,810</td>
<td>22.2%</td>
<td>-27.4%</td>
<td>22,803</td>
<td>3.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>17</td>
<td>16</td>
<td>CEPHALEXIN</td>
<td>24,105</td>
<td>-0.9%</td>
<td>-18.6%</td>
<td>22,763</td>
<td>3.0%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>18</td>
<td>19</td>
<td>BENZTROPINE MESYLATE</td>
<td>56,129</td>
<td>-0.3%</td>
<td>-3.5%</td>
<td>22,536</td>
<td>2.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>19</td>
<td>18</td>
<td>LISINOPRIL</td>
<td>32,479</td>
<td>2.9%</td>
<td>-15.9%</td>
<td>21,865</td>
<td>2.8%</td>
<td>0.1%</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
<td>FOLIC ACID</td>
<td>28,812</td>
<td>-7.0%</td>
<td>-17.3%</td>
<td>17,559</td>
<td>2.3%</td>
<td>-0.1%</td>
</tr>
</tbody>
</table>
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, ¼, 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: 4TH QUARTER 2016

Utilization of physician-administered drugs during the fourth quarter of 2016 (October – December 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 Q3) and Table 2 shows the comparison to the prior-year quarter (2015 Q4).

**Table 1: 2016 Q4 Physician-Administered Drugs: Change from 2016 Q3 (one quarter)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Total Utilizing Beneficiaries</th>
<th>% Change from 2016 Q3</th>
<th>Total Paid Claims</th>
<th>% Change from 2016 Q3</th>
<th>Total Reimbursement Dollars Paid</th>
<th>% Change from 2016 Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)</td>
<td>24,698</td>
<td>7.5%</td>
<td>35,597</td>
<td>1.6%</td>
<td>$894,503</td>
<td>-3.6%</td>
</tr>
<tr>
<td>PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED</td>
<td>253,779</td>
<td>-10.2%</td>
<td>580,322</td>
<td>-11.3%</td>
<td>$54,341,752</td>
<td>-22.8%</td>
</tr>
<tr>
<td>MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)</td>
<td>94,816</td>
<td>-10.5%</td>
<td>194,928</td>
<td>-11.0%</td>
<td>$2,248,168</td>
<td>-10.0%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>373,293</td>
<td>-9.3%</td>
<td>810,847</td>
<td>-10.7%</td>
<td>$57,484,423</td>
<td>-22.1%</td>
</tr>
</tbody>
</table>

**Table 2: 2016 Q4 Physician-Administered Drugs: Change from 2015 Q4 (one year)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Total Utilizing Beneficiaries</th>
<th>% Change from 2015 Q4</th>
<th>Total Paid Claims</th>
<th>% Change from 2015 Q4</th>
<th>Total Reimbursement Dollars Paid</th>
<th>% Change from 2015 Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)</td>
<td>24,698</td>
<td>-18.5%</td>
<td>35,597</td>
<td>-16.9%</td>
<td>$894,503</td>
<td>-7.2%</td>
</tr>
<tr>
<td>PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED</td>
<td>253,779</td>
<td>-11.0%</td>
<td>580,322</td>
<td>-15.2%</td>
<td>$54,341,752</td>
<td>-26.1%</td>
</tr>
<tr>
<td>MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)</td>
<td>94,816</td>
<td>-25.9%</td>
<td>194,928</td>
<td>-28.7%</td>
<td>$2,248,168</td>
<td>-27.8%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>373,293</td>
<td>-15.8%</td>
<td>810,847</td>
<td>-19.0%</td>
<td>$57,484,423</td>
<td>-26.0%</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Rank</th>
<th>Last Year Rank</th>
<th>HCPCS Code</th>
<th>Drug Description</th>
<th>2016 Q4 Total Utilizing Beneficiaries</th>
<th>% Change Total Utilizing Beneficiaries from 2016 Q3</th>
<th>% Change Total Utilizing Beneficiaries from 2015 Q4</th>
<th>2016 Q4 Total Reimbursement Dollars Paid</th>
<th>2016 Q4 Total Paid Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>J3490</td>
<td>MEDROXYPROGESTERONE ACETATE</td>
<td>39,195</td>
<td>-6.1%</td>
<td>-12.1%</td>
<td>$2,591,571</td>
<td>40,028</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>J3490</td>
<td>LEVONORGESTREL</td>
<td>25,886</td>
<td>-15.0%</td>
<td>-16.1%</td>
<td>$650,257</td>
<td>27,044</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>S4993</td>
<td>LEVONORGESTREL-ETHIN ESTRADIOL</td>
<td>20,393</td>
<td>-10.1%</td>
<td>-9.9%</td>
<td>$2,421,385</td>
<td>20,760</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>J2405</td>
<td>ONDANSETRON HCL/PF</td>
<td>19,018</td>
<td>-12.6%</td>
<td>-16.1%</td>
<td>$107,875</td>
<td>20,056</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>J3490</td>
<td>ULIPRISTAL ACETATE</td>
<td>19,018</td>
<td>-12.3%</td>
<td>-25.0%</td>
<td>$528,809</td>
<td>23,796</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>J1885</td>
<td>KETOROLAC TROMETHAMINE</td>
<td>16,811</td>
<td>-11.4%</td>
<td>-10.2%</td>
<td>$102,044</td>
<td>20,056</td>
</tr>
<tr>
<td>7</td>
<td>13</td>
<td>X7700</td>
<td>0.9 % SODIUM CHLORIDE</td>
<td>14,305</td>
<td>-7.6%</td>
<td>-4.7%</td>
<td>$363,305</td>
<td>23,493</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>J2270</td>
<td>MORPHINE SULFATE</td>
<td>10,581</td>
<td>-6.8%</td>
<td>13.7%</td>
<td>$52,034</td>
<td>11,018</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>J0696</td>
<td>CEFTIRAXONE SODIUM</td>
<td>9,696</td>
<td>-7.9%</td>
<td>-6.9%</td>
<td>$56,454</td>
<td>10,613</td>
</tr>
<tr>
<td>10</td>
<td>13</td>
<td>J7307</td>
<td>ETENOGESTREL</td>
<td>9,645</td>
<td>3.6%</td>
<td>3.3%</td>
<td>$7,003,926</td>
<td>9,645</td>
</tr>
<tr>
<td>11</td>
<td>12</td>
<td>Z7610</td>
<td>ACETAMINOPHEN</td>
<td>9,506</td>
<td>-4.1%</td>
<td>0.3%</td>
<td>$79,666</td>
<td>11,170</td>
</tr>
<tr>
<td>12</td>
<td>9</td>
<td>S4993</td>
<td>NORGESTIMATE-ETHINYL ESTRADIOL</td>
<td>8,676</td>
<td>-11.9%</td>
<td>-20.0%</td>
<td>$968,886</td>
<td>8,872</td>
</tr>
<tr>
<td>13</td>
<td>8</td>
<td>J1100</td>
<td>DEXAMETHASONE SOD PHOSPHATE</td>
<td>7,299</td>
<td>-9.0%</td>
<td>-16.9%</td>
<td>$57,629</td>
<td>7,616</td>
</tr>
<tr>
<td>14</td>
<td>11</td>
<td>J1170</td>
<td>HYDROMORPHONE HCL</td>
<td>6,933</td>
<td>3.0%</td>
<td>-14.8%</td>
<td>$46,030</td>
<td>8,966</td>
</tr>
<tr>
<td>15</td>
<td>16</td>
<td>J1100</td>
<td>Dexmethasone sod phosphate</td>
<td>6,933</td>
<td>3.0%</td>
<td>-14.8%</td>
<td>$46,030</td>
<td>8,966</td>
</tr>
<tr>
<td>16</td>
<td>11</td>
<td>J1170</td>
<td>HYDROMORPHONE HCL</td>
<td>6,786</td>
<td>-17.3%</td>
<td>-29.4%</td>
<td>$55,161</td>
<td>9,017</td>
</tr>
<tr>
<td>17</td>
<td>18</td>
<td>Z7610</td>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>6,404</td>
<td>-16.8%</td>
<td>-15.2%</td>
<td>$68,629</td>
<td>6,993</td>
</tr>
<tr>
<td>18</td>
<td>23</td>
<td>S0191</td>
<td>MISOPROSTOL</td>
<td>6,054</td>
<td>-1.9%</td>
<td>4.5%</td>
<td>$9,786</td>
<td>6,121</td>
</tr>
<tr>
<td>19</td>
<td>17</td>
<td>J3010</td>
<td>FENTANYL CITRATE/PF</td>
<td>5,942</td>
<td>-15.2%</td>
<td>-22.1%</td>
<td>$29,575</td>
<td>5,969</td>
</tr>
<tr>
<td>20</td>
<td>19</td>
<td>J7303</td>
<td>ETONOGESTREL/ETHINYL ESTRADIOL</td>
<td>5,942</td>
<td>-7.7%</td>
<td>-16.5%</td>
<td>$608,812</td>
<td>5,969</td>
</tr>
</tbody>
</table>
### Table 4: Top 20 Physician-Administered Drugs by Total Reimbursement Dollars Paid

<table>
<thead>
<tr>
<th>Rank</th>
<th>Last Year Rank</th>
<th>HCPCS Code</th>
<th>Drug Description</th>
<th>2016 Q4 Total Reimbursement Dollars Paid</th>
<th>% Change Total Reimbursement Dollars from 2016 Q3</th>
<th>% Change Total Reimbursement Dollars from 2015 Q4</th>
<th>2016 Q4 Total Utilizing Beneficiaries</th>
<th>2016 Q4 Total Paid Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>J7307</td>
<td>ETONOGESTREL</td>
<td>$7,003,926</td>
<td>4.0%</td>
<td>3.7%</td>
<td>9,645</td>
<td>9,645</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>J3490</td>
<td>MEDROXYPROGESTERONE ACETATE</td>
<td>$2,591,571</td>
<td>-4.2%</td>
<td>-11.7%</td>
<td>39,195</td>
<td>40,028</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>J9355</td>
<td>TRASTUZUMAB</td>
<td>$2,544,579</td>
<td>-3.9%</td>
<td>-5.2%</td>
<td>262</td>
<td>879</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>S4993</td>
<td>LEVONORGESTREL-ETHIN ESTRADIOL</td>
<td>$2,421,385</td>
<td>-11.7%</td>
<td>-10.4%</td>
<td>20,393</td>
<td>20,760</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
<td>J7300</td>
<td>INTRAUTERINE COPPER CONTRACEPTIVE</td>
<td>$2,155,533</td>
<td>3.4%</td>
<td>-11.7%</td>
<td>3,295</td>
<td>3,313</td>
</tr>
<tr>
<td>6</td>
<td>10</td>
<td>Q4081</td>
<td>EPOETIN ALFA (100 UNITS)</td>
<td>$2,079,063</td>
<td>7.9%</td>
<td>-4.9%</td>
<td>1,950</td>
<td>40,854</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>J1745</td>
<td>INFliximab</td>
<td>$2,031,208</td>
<td>-11.6%</td>
<td>5.9%</td>
<td>453</td>
<td>918</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>J7192</td>
<td>ANTIHEMOP. FVIII, FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)</td>
<td>$1,851,703</td>
<td>0.4%</td>
<td>-23.8%</td>
<td>60</td>
<td>187</td>
</tr>
<tr>
<td>9</td>
<td>7</td>
<td>J2505</td>
<td>PEGFILGRASTIM</td>
<td>$1,676,287</td>
<td>-1.1%</td>
<td>-32.2%</td>
<td>234</td>
<td>483</td>
</tr>
<tr>
<td>10</td>
<td>14</td>
<td>J1300</td>
<td>ECULIZUMAB</td>
<td>$1,474,586</td>
<td>3.2%</td>
<td>-8.1%</td>
<td>23</td>
<td>130</td>
</tr>
<tr>
<td>11</td>
<td>11</td>
<td>J9019</td>
<td>ASPARAGINASE (ERWINIA CHRYSAN)</td>
<td>$1,403,765</td>
<td>3.0%</td>
<td>-35.1%</td>
<td>21</td>
<td>159</td>
</tr>
<tr>
<td>12</td>
<td>13</td>
<td>J7304</td>
<td>NORELGESTRONIN/ETHIN. ESTRADIOL</td>
<td>$1,320,240</td>
<td>-9.7%</td>
<td>-25.1%</td>
<td>3,878</td>
<td>3,914</td>
</tr>
<tr>
<td>13</td>
<td>20</td>
<td>J9306</td>
<td>PERTUZUMAB</td>
<td>$1,223,549</td>
<td>4.3%</td>
<td>26.5%</td>
<td>100</td>
<td>762</td>
</tr>
<tr>
<td>14</td>
<td>16</td>
<td>J9035</td>
<td>BEVACIZUMAB</td>
<td>$1,102,023</td>
<td>-0.8%</td>
<td>-25.0%</td>
<td>141</td>
<td>414</td>
</tr>
<tr>
<td>15</td>
<td>25</td>
<td>J9266</td>
<td>PEGASPARGASE</td>
<td>$1,000,050</td>
<td>-20.5%</td>
<td>27.5%</td>
<td>111</td>
<td>153</td>
</tr>
<tr>
<td>16</td>
<td>18</td>
<td>S4993</td>
<td>NORGESTIMATE-ETHINYL ESTRADIOL</td>
<td>$968,886</td>
<td>-11.9%</td>
<td>-21.2%</td>
<td>8,676</td>
<td>8,872</td>
</tr>
<tr>
<td>17</td>
<td>27</td>
<td>J7301</td>
<td>LEVONORGESTREL</td>
<td>$944,333</td>
<td>-4.1%</td>
<td>36.5%</td>
<td>1,464</td>
<td>1,466</td>
</tr>
<tr>
<td>18</td>
<td>2</td>
<td>J7189</td>
<td>COAGULATION FACTOR VIIA, RECOMB (NOVOSEVEN®)</td>
<td>$935,643</td>
<td>-90.4%</td>
<td>-85.1%</td>
<td>27</td>
<td>44</td>
</tr>
<tr>
<td>19</td>
<td>15</td>
<td>90378</td>
<td>PALIVIZUMAB³</td>
<td>$920,426</td>
<td>N/A</td>
<td>-38.4%</td>
<td>258</td>
<td>443</td>
</tr>
<tr>
<td>20</td>
<td>23</td>
<td>J9310</td>
<td>RITUXIMAB</td>
<td>$780,955</td>
<td>-17.2%</td>
<td>-3.0%</td>
<td>132</td>
<td>244</td>
</tr>
</tbody>
</table>

¹ There were a total of 197 paid claims for this drug in 2016 Q3, compared with 44 paid claims in 2016 Q4.
² PALIVIZUMAB is authorized for use only between November and the following March, so there are no claims for PALIVIZUMAB during Q3 (July 1 through September 30).

NOTE: Effective October 1, 2016, HCPCS code J7302 (levonorgestrel-releasing intrauterine contraceptive system, 52 mg) has been replaced by codes J7297 (levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 3 year duration) and J7928 (levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 5 year duration). HCPCS code J7302 has consistently been in the Top 20 on this table, ranking 3rd both last quarter and the prior-year quarter.
<table>
<thead>
<tr>
<th>Rank</th>
<th>Last Year Rank</th>
<th>HCPCS Code</th>
<th>Drug Description</th>
<th>2016 Q4 Reimbursement Dollars Paid per Utilizing Beneficiary</th>
<th>% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2016 Q3</th>
<th>% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2015 Q4</th>
<th>2016 Q4 Total Reimbursement Dollars Paid</th>
<th>2016 Q4 Total Utilizing Beneficiaries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>J7181</td>
<td>FACTOR XIII A-SUBUNIT, RECOMB (TRETEN®)</td>
<td>$169,269</td>
<td>24.9%</td>
<td>65.8%</td>
<td>$338,538</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>N/A</td>
<td>J7199</td>
<td>FACTOR IX RECOM, ALBUMIN FUSION (INDELVION®)</td>
<td>$166,488</td>
<td>27.8%</td>
<td>N/A</td>
<td>$332,977</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>J7201</td>
<td>FACTOR IX REC, FC FUSION PROTN (ALPROLIX®)</td>
<td>$118,102</td>
<td>35.5%</td>
<td>-37.6%</td>
<td>$354,305</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>J1458</td>
<td>GALSULFASE</td>
<td>$112,240</td>
<td>27.8%</td>
<td>N/A</td>
<td>$332,977</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
<td>J1322</td>
<td>ELOSULFASE ALFA</td>
<td>$97,859</td>
<td>-10.4%</td>
<td>36.9%</td>
<td>$489,295</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>10</td>
<td>J1743</td>
<td>IDURSULFASE</td>
<td>$93,732</td>
<td>-4.0%</td>
<td>24.0%</td>
<td>$749,857</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>N/A</td>
<td>J9307</td>
<td>PRALATREXATE²</td>
<td>$91,777</td>
<td>-10.4%</td>
<td>36.9%</td>
<td>$489,295</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>16</td>
<td>J9019</td>
<td>ASPARAGINASE (ERWINIA CHRYSAN)</td>
<td>$66,846</td>
<td>17.7%</td>
<td>N/A</td>
<td>$1,403,765</td>
<td>21</td>
</tr>
<tr>
<td>9</td>
<td>13</td>
<td>J1300</td>
<td>ECULIZUMAB</td>
<td>$64,112</td>
<td>21.2%</td>
<td>-27.5%</td>
<td>$1,474,586</td>
<td>23</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
<td>J7195</td>
<td>FACTOR IX HUMAN RECOMBINANT (BENEFIX®)</td>
<td>$61,637</td>
<td>78.2%</td>
<td>26.2%</td>
<td>$61,637</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>19</td>
<td>J0221</td>
<td>ALGLUCOSIDASE ALFA</td>
<td>$49,799</td>
<td>-12.1%</td>
<td>16.1%</td>
<td>$149,396</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>17</td>
<td>J7205</td>
<td>ANTIHEMOPH.FVIII REC, FC FUSION (ELOCTATE®)</td>
<td>$49,646</td>
<td>-15.8%</td>
<td>2.3%</td>
<td>$446,815</td>
<td>9</td>
</tr>
<tr>
<td>13</td>
<td>N/A</td>
<td>C9137</td>
<td>ANTIHEMO.FVIII,FULL LENGTH PEG (ADYNOVATE®)</td>
<td>$43,490</td>
<td>34.6%</td>
<td>N/A</td>
<td>$43,490</td>
<td>1</td>
</tr>
<tr>
<td>14</td>
<td>22</td>
<td>J3385</td>
<td>VELAGLUCERASE ALFA</td>
<td>$38,561</td>
<td>18.3%</td>
<td>-11.9%</td>
<td>$38,561</td>
<td>1</td>
</tr>
<tr>
<td>15</td>
<td>11</td>
<td>J7185</td>
<td>ANTIHEMOPH.FVIII,B-DOMAIN DEL (XYNTHA®)</td>
<td>$37,847</td>
<td>-55.6%</td>
<td>8.3%</td>
<td>$189,237</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>3</td>
<td>J7189</td>
<td>COAGULATION FACTOR VILLA,RECOMB (NOVOSEVEN®)</td>
<td>$34,653</td>
<td>-85.8%</td>
<td>67.1%</td>
<td>$935,643</td>
<td>27</td>
</tr>
<tr>
<td>17</td>
<td>27</td>
<td>J1931</td>
<td>LARONIDASE</td>
<td>$32,928</td>
<td>50.3%</td>
<td>-0.9%</td>
<td>$98,783</td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td>39</td>
<td>J7183</td>
<td>ANTIHEMOPHILIC FACTOR/VWF (WILATE®)</td>
<td>$32,620</td>
<td>79.2%</td>
<td>38.2%</td>
<td>$64,519</td>
<td>2</td>
</tr>
<tr>
<td>19</td>
<td>24</td>
<td>J7192</td>
<td>ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)</td>
<td>$30,862</td>
<td>0.4%</td>
<td>0.0%</td>
<td>$1,851,703</td>
<td>60</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
<td>J9228</td>
<td>IPILIMUMAB</td>
<td>$29,115</td>
<td>69.4%</td>
<td>-59.8%</td>
<td>$29,115</td>
<td>1</td>
</tr>
</tbody>
</table>

¹This drug was added as a Medi-Cal benefit effective for dates of service on or after April 1, 2016.
²This drug only had one utilizing beneficiaries in 2016 Q4, three utilizing beneficiaries in 2016 Q3, and none in 2015 Q4.
³This drug was added as a Medi-Cal benefit effective for dates of service on or after July 1, 2016.
DATE OF REVIEW: April 11, 2017

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:
- ANALGESICS, NARCOTICS
- ANTIHYPERTENSIVES, ACE INHIBITORS
- ANTI-INFLAMMATORY, INTERLEUKIN-1 BETA BLOCKERS
- ANTINEOPLASTIC - ALKYLATING AGENTS
- ANTIVIRALS, HIV-SPECIFIC, CCR5 CO-RECEPTOR ANTAG.
- GENERAL ANESTHETICS, INJECTABLE
- POTASSIUM REPLACEMENT
- SMOKING DETERRENT AGENTS (GANGLIONIC STIM, OTHERS)

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.

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:
- Review list of GCNs with prospective DUR alerts turned on between January 1, 2017 and March 31, 2017 (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.
### Table 1. New GCNs for Existing DUR Target Drugs: Q1 2017 (1/1/17 – 3/31/17).

<table>
<thead>
<tr>
<th>Date</th>
<th>GCN</th>
<th>Drug Description</th>
<th>Additional Alerts Turned on</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/11/2017</td>
<td>076651</td>
<td>MELPHALAN HCL/BETADEX SBES</td>
<td>PG</td>
</tr>
<tr>
<td></td>
<td>076637</td>
<td>ENALAPRIL MALEATE</td>
<td>DA, PG, TD, LR, ID, HD, LD</td>
</tr>
<tr>
<td>2/2/2017</td>
<td>067915</td>
<td>FENTANYL CITRAT/DEXTROSE 5%/PF</td>
<td>DA, MC, TD, AT, ID, HD, LD</td>
</tr>
<tr>
<td></td>
<td>069931</td>
<td>FENTANYL CITRATE-0.9 % NACL/PF</td>
<td>DA, MC, TD, AT, ID, HD, LD</td>
</tr>
<tr>
<td>2/8/2017</td>
<td>077086</td>
<td>MARAVIROC</td>
<td>PG</td>
</tr>
<tr>
<td></td>
<td>077087</td>
<td></td>
<td>MC</td>
</tr>
<tr>
<td>2/22/2017</td>
<td>069304</td>
<td>POTASSIUM CL/LIDO/0.9 % NACL</td>
<td>MC, TD, ID, HD</td>
</tr>
<tr>
<td>3/2/2017</td>
<td>068087</td>
<td>MIDAZOLAM IN D5W</td>
<td>PG</td>
</tr>
<tr>
<td></td>
<td>068694</td>
<td>MIDAZOLAM HCL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>068695</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/8/2017</td>
<td>077135</td>
<td>MORPHINE SULFATE IN 0.9 % NACL</td>
<td>DA, MC, TD, AT, ID, HD, LD</td>
</tr>
<tr>
<td></td>
<td>077141</td>
<td>NICOTINE POLACRILEX</td>
<td>PG</td>
</tr>
<tr>
<td>3/15/2017</td>
<td>077053</td>
<td>MORPHINE SULFATE</td>
<td>DA, MC, TD, AT, ID, HD, LD</td>
</tr>
<tr>
<td></td>
<td>077054</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>077055</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DATE OF REVIEW: April 11, 2017

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:
- ANTIPSYCHOTICS, ATYPICAL, DOPAMINE,& SEROTONIN ANTAG

DRUG PROBLEM TYPE: Ingredient Duplication (ID)

BACKGROUND: Once a claim is deemed reimbursable through the Medi-Cal fee-for-service (FFS) program, DUR processing begins. Following the criteria established by DHCS and the DUR Board, drugs are compared to the patient’s medical and pharmacy claims history file for select drug therapy problems. DUR alert messages are returned to the pharmacist for all problems detected by this review. When setting criteria for prospective DUR, it is important to consider the implications of alert fatigue, which can lead to a routine override of alerts without processing the reasoning behind the alert. If the system is generating too many alerts, clinically important alerts may be overlooked inadvertently.

ISSUES: A systematic review of each prospective DUR alert generated in 2016 by the Medi-Cal fee-for-service prospective DUR program was conducted. This review revealed that quetiapine + ingredient duplication was responsible for the top drug/alert combination, by volume of alerts. The ingredient duplication alert occurs when a claim is submitted for a drug that contains a systemically-absorbed drug that chemically duplicates a drug currently in the patient’s active paid claims medication history.

- Ranked 1st by volume of alerts in 2016:
  - Quetiapine + ingredient duplication (ID) alert = 198,982 alerts
  - Represents 22% of the 898,937 ingredient duplication alerts that year
  - 100% of adjudicated alerts are overrides

In addition, in Section 20 of the Medi-Cal Prospective Drug Use Review Manual there is no list of drugs in which the ID alert is active and no guidelines for how drugs are selected for inclusion in the ID alert, other than that they must appear on the main target drug list (TDL) for prospective DUR.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: All ingredient (ID) alerts for quetiapine with dates of service between January 1, 2016 and December 31, 2016 were reviewed. A review of the breakdown of ID alerts by formulation and dose is shown in Table 1.
Table 1. Ingredient Duplication Alerts for Quetiapine during 2016, stratified by formulation and dose.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Dose</th>
<th>Total ID Alerts n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quetiapine (Immediate Release)</td>
<td>25 mg</td>
<td>30,688 (15%)</td>
</tr>
<tr>
<td></td>
<td>50 mg</td>
<td>2,750 (1%)</td>
</tr>
<tr>
<td></td>
<td>100 mg</td>
<td>43,148 (22%)</td>
</tr>
<tr>
<td></td>
<td>200 mg</td>
<td>31,777 (16%)</td>
</tr>
<tr>
<td></td>
<td>300 mg</td>
<td>28,513 (14%)</td>
</tr>
<tr>
<td></td>
<td>400 mg</td>
<td>24,468 (12%)</td>
</tr>
<tr>
<td>Quetiapine (Extended Release)</td>
<td>50 mg</td>
<td>6,207 (3%)</td>
</tr>
<tr>
<td></td>
<td>150 mg</td>
<td>5,185 (3%)</td>
</tr>
<tr>
<td></td>
<td>200 mg</td>
<td>6,979 (4%)</td>
</tr>
<tr>
<td></td>
<td>300 mg</td>
<td>9,736 (5%)</td>
</tr>
<tr>
<td></td>
<td>400 mg</td>
<td>9,531 (5%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>198,982</strong></td>
</tr>
</tbody>
</table>

Concomitant use of multiple doses of quetiapine is not contraindicated. Clinical guidelines for quetiapine monotherapy recommend that the dose be changed in increments of 25 mg, 50 mg, and/or 100 mg, depending on patient response and tolerability, until optimum benefit is reached. Additionally, when tapering or using as adjunctive therapy, gradual titration is recommended for patient safety reasons.

Finally, there are 138 drugs that generated ID alerts in 2016, with only 57 drugs responsible for more than 1,000 ID alerts during the year. The remaining top 20 drugs (besides quetiapine) for ID alerts by volume include:

- ACETAMINOPHEN
- ALBUTEROL
- ARIPIPRAZOLE
- BENZTROPINE
- CHLORPROMAZINE
- CLOzapine
- DIVALPROEX
- EMTRICITABINE
- GABAPENTIN
- HALOPERIDOL
- LEVOThYRoxINE
- LITHIUM
- LURASIDONE
- NOREThINDRONe-ESTRADIOL-IRON
- OLANZAPINE
- PALIPERIDONE
- RISPERIDONE
- SERTrALINE
- ZIPRASIDONE

**ProposalD InterventioN RecommeNDation to the DUR Board:**

- Discuss the risks and benefits of turning off the ingredient duplication (ID) alert for quetiapine.
- Discuss the merits of completing a similar evaluation for the list of drugs in which the ID alert is active (alert status is on) and ID alerts were generated in 2016. An in-depth prospective DUR review could also include clean-up of this alert, as there are many more drugs with the alert turned on than generate alerts.
- 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.
PROSPECTIVE DUR REVIEW

DATE OF REVIEW: January 5, 2016 and April 11, 2017

AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) THERAPEUTIC CATEGORY:
- Reviewed all drugs.

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:
- Reviewed all drugs.

DRUG PROBLEM TYPE: Underutilization (LR)

BACKGROUND: In the Medi-Cal System, the underutilization (late refill) screening generates an alert when a sub-therapeutic pattern of prescription drug use is detected. Alerts are generated when patients fail to renew prescriptions for selected maintenance drugs before more than 125% of the days' supply of the previous prescription has been used.

Example: A 30-day supply of a medication was filled on January 1, 2017 (30 days * 125% = 37.5 days), so if a beneficiary fills the next refill of that medication on the 38th day it will generate an underutilization (LR) alert.

ISSUES: Late refill (LR) alert is the 4th most common alert by total number of alerts in the Medi-Cal fee-for-service program. By allowing overrides of all LR alerts, access to needed medications is improved, but may result in safety issues for beneficiaries who are not adhering to their medication regimen and/or unnecessary costs (the direct costs of medications and costs attributed to adverse effects from poor adherence). As we try to balance alert fatigue and quality of care in prospective DUR, a more in-depth look at these alerts may prove helpful in determining the best course of action to take, if any.

For reference, the late refill alert is currently turned on for the following drugs:

<table>
<thead>
<tr>
<th>Amlodipine</th>
<th>Clonidine</th>
<th>Fluvastatin</th>
<th>Metoprolol</th>
<th>Simvastatin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole</td>
<td>Clorazapine</td>
<td>Furosemide</td>
<td>Mirtazapine</td>
<td>Somatropin</td>
</tr>
<tr>
<td>Asenapine</td>
<td>Desipramine</td>
<td>Gabapentin</td>
<td>Nifedipine</td>
<td>Thiothixene</td>
</tr>
<tr>
<td>Atenolol</td>
<td>Desvenlafaxine</td>
<td>Glipizide</td>
<td>Olanzapine</td>
<td>Trifluoperazine</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>Digoxin</td>
<td>Glyburide</td>
<td>Paliperidone</td>
<td>Valproic acid</td>
</tr>
<tr>
<td>Benazepril</td>
<td>Diltiazem</td>
<td>Haloperidol</td>
<td>Paroxetine</td>
<td>Venlafaxine</td>
</tr>
<tr>
<td>Benztropine</td>
<td>Diltiazem</td>
<td>Haloperidol</td>
<td>Paroxetine</td>
<td>Venlafaxine</td>
</tr>
<tr>
<td>Bupropion</td>
<td>Duloxetine</td>
<td>Imipramine</td>
<td>Pimozide</td>
<td>Vioxx</td>
</tr>
<tr>
<td>Buspirone</td>
<td>Enalapril</td>
<td>Levomilnacipran</td>
<td>Phenytoin</td>
<td>Vortioxetine</td>
</tr>
<tr>
<td>Captopril</td>
<td>Escitalopram</td>
<td>Levothryroxine</td>
<td>Pioglitazone</td>
<td>Ziprasidone</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Etanercept</td>
<td>Lithium</td>
<td>Quetiapine</td>
<td>Ziprasidone</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>Fluphenazine</td>
<td>Lovastatin</td>
<td>Risperidone</td>
<td>Ziprasidone</td>
</tr>
<tr>
<td>Citalopram</td>
<td>Fluvoxamine</td>
<td>Loxapine</td>
<td>Rosiglitazone</td>
<td>Ziprasidone</td>
</tr>
<tr>
<td>Clomipramine</td>
<td>Fluoxetine</td>
<td>Lurasidone</td>
<td>Sertraline</td>
<td>Ziprasidone</td>
</tr>
</tbody>
</table>
REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE PROSPECTIVE DUR CRITERIA:
Between January 1, 2016, and December 31, 2016 a total of 469,956 LR alerts were generated by pharmacy claims processed in the Medi-Cal fee-for-service program. Of these, a total of 400,566 (85.2%) were overridden by providers at the point-of-service, resulting in a paid claim. A review of the LR alert data by the length of time the prescription was late found that of the claims with LR alert overrides, 51.3% were within the first seven days of generating the LR alert.

As shown in Table 1, the timing of LR alert overrides for medications went up to the 11th-week after the 125% cutoff for generating the LR alert. Using the example listed above, the refill that was due for dispensing on January 31, 2017, would end up being filled at the end of April, 11 weeks after the 8-day buffer allowed before the claim generated the LR alert.

Table 1. Status of all Late Refill (LR) Alert Overrides during 2016.

<table>
<thead>
<tr>
<th>Weeks past the 125% cutoff</th>
<th>Status of Alert</th>
<th>Total Alerts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjudicated</td>
<td>Not Adjudicated</td>
</tr>
<tr>
<td></td>
<td>Overridden</td>
<td>Cancelled</td>
</tr>
<tr>
<td>1</td>
<td>205,401</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>101,664</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>72,585</td>
<td>18</td>
</tr>
<tr>
<td>4</td>
<td>10,647</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>2,854</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>2,223</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>1,849</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>1,321</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>1,267</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>668</td>
<td>0</td>
</tr>
<tr>
<td>11</td>
<td>87</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>400,566</strong></td>
<td><strong>74</strong></td>
</tr>
</tbody>
</table>
The top 20 drugs by total LR alert overrides during this time period are shown in Table 2, along with the total number of paid claims for each drug during FFY 2015.

Table 2. Top 20 Drugs by Total Late Refill (LR) Alert Overrides during 2016.

<table>
<thead>
<tr>
<th></th>
<th>Drug</th>
<th>Week 1 Overrides</th>
<th>Total Overrides</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QUETIAPINE FUMARATE</td>
<td>36,712</td>
<td>70,504</td>
<td>52.1%</td>
</tr>
<tr>
<td>2</td>
<td>ARIPIPRAZOLE</td>
<td>32,622</td>
<td>62,913</td>
<td>51.9%</td>
</tr>
<tr>
<td>3</td>
<td>RISPERIDONE</td>
<td>23,467</td>
<td>45,003</td>
<td>52.1%</td>
</tr>
<tr>
<td>4</td>
<td>OLANZAPINE</td>
<td>18,497</td>
<td>33,893</td>
<td>54.6%</td>
</tr>
<tr>
<td>5</td>
<td>BENZTROPINE MESYLATE</td>
<td>13,026</td>
<td>24,683</td>
<td>52.8%</td>
</tr>
<tr>
<td>6</td>
<td>LURASIDONE HCL</td>
<td>10,738</td>
<td>20,616</td>
<td>52.1%</td>
</tr>
<tr>
<td>7</td>
<td>LITHIUM</td>
<td>8,989</td>
<td>17,051</td>
<td>52.7%</td>
</tr>
<tr>
<td>8</td>
<td>HALOPERIDOL</td>
<td>6,280</td>
<td>11,480</td>
<td>54.7%</td>
</tr>
<tr>
<td>9</td>
<td>ZIPRASIDONE HCL</td>
<td>5,733</td>
<td>11,112</td>
<td>51.6%</td>
</tr>
<tr>
<td>10</td>
<td>ATORVASTATIN CALCIUM</td>
<td>5,239</td>
<td>11,438</td>
<td>45.8%</td>
</tr>
<tr>
<td>11</td>
<td>LEVOTHYROXINE SODIUM</td>
<td>5,011</td>
<td>10,251</td>
<td>48.9%</td>
</tr>
<tr>
<td>12</td>
<td>AMLODIPINE</td>
<td>4,666</td>
<td>10,735</td>
<td>43.5%</td>
</tr>
<tr>
<td>13</td>
<td>VALPROIC ACID</td>
<td>4,480</td>
<td>7,769</td>
<td>57.7%</td>
</tr>
<tr>
<td>14</td>
<td>PALIPERIDONE</td>
<td>4,202</td>
<td>7,685</td>
<td>54.7%</td>
</tr>
<tr>
<td>15</td>
<td>CLOZAPINE</td>
<td>3,948</td>
<td>5,147</td>
<td>76.7%</td>
</tr>
<tr>
<td>16</td>
<td>SERTRALINE HCL</td>
<td>3,771</td>
<td>7,556</td>
<td>49.9%</td>
</tr>
<tr>
<td>17</td>
<td>GABAPENTIN</td>
<td>3,552</td>
<td>7,548</td>
<td>47.1%</td>
</tr>
<tr>
<td>18</td>
<td>SIMVASTATIN</td>
<td>3,037</td>
<td>7,616</td>
<td>39.9%</td>
</tr>
<tr>
<td>19</td>
<td>METOPROLOL</td>
<td>2,956</td>
<td>6,623</td>
<td>44.6%</td>
</tr>
<tr>
<td>20</td>
<td>FUROSEMIDE</td>
<td>2,830</td>
<td>5,941</td>
<td>47.6%</td>
</tr>
</tbody>
</table>

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Discuss the risks and benefits of increasing the threshold for the late refill (LR) alert from 125% to 150%.
- Discuss the risks and benefits of either eliminating the late refill (LR) alert or changing to a text-only alert for certain drugs and/or classes of drugs.
- Discuss the merits of addressing the clinical impact of late refills using academic detailing. A proposal could be drafted that would focus on a particular drug and/or region in California for a pilot project to assess feasibility and acceptability of academic detailing as another option for educational outreach to providers.
- Review the LR target drug list for potential drugs or drug therapeutic categories needing additional evaluation.
- 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.
PROSPECTIVE DUR REVIEW

DATE OF REVIEW: January 17, 2017 and April 11, 2017

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- Reviewed all drugs.

DRUG PROBLEM TYPE: Clinical Misuse/Additive Toxicity (AT)

BACKGROUND: In the current Medi-Cal DUR system, the additive toxicity (AT) alert is generated when a patient reaches a threshold of four active prescriptions for any combination of drugs in specified therapeutic classes. Section 35 of the Medi-Cal DUR Manual specifies that the AT alert should be on for Scheduled pain medications and/or psychotropics.

On August 31, 2016, the U.S. Food and Drug Administration (FDA) announced that it will require class-wide changes to drug labeling, including patient information, to help inform health care providers and patients of the serious risks associated with the use of certain opioid medications in combination with benzodiazepines and other central nervous system (CNS) depressants. At the November 15, 2016, DUR Board meeting, it was suggested that by updating the AT alert to focus on opioids, benzodiazepines, and other CNS depressants, the AT alert could be an effective tool to help providers identify patients who may be at high-risk for serious adverse events.

ISSUES: At the February 21, 2017, DUR Board meeting, recommendations for the drugs to include in the AT alert were determined, except for 32 drugs, which the DUR Board agreed to discuss further outside of the DUR Board meeting. These drugs were not on the FDA list of CNS Depressants and included drugs that either had a CNS depressant effect and/or were in the same class of drugs as other drugs listed on the FDA list of CNS Depressants.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE PROSPECTIVE DUR CRITERIA:

- SSRIs: Keep or turn OFF Additive Toxicity (AT) alerts for this class of drugs, based on side effect profile
  - CITALOPRAM – turn off
  - ESCITALOPRAM – turn off
  - FLUOXETINE – turn off
  - FLUVOXAMINE – turn off
  - PAROXETINE – turn off
  - SERTRALINE – turn off
  - VILAZODONE – keep off
  - VORTIOXETINE – turn off

- SNRIs: Keep or turn ON AT alerts for this class of drugs, based on side effect profile
  - DESVENLAFAXINE – keep on
  - DULOXETINE – keep on
  - LEVOMILNACIPRAN – keep on
  - VENLAFAXINE – turn on
• TRICYCLICs: Keep or turn ON AT alerts for this class of drugs, based on side effect profile
  o AMITRIPTYLINE – keep on
  o CLOMIPRAMINE - keep on
  o DESIPRAMINE – keep on
  o DOXEPIN – keep on
  o IMIPRAMINE – keep on
  o NORTRIPTYLNE – keep on
  o PROTRIPTYLINE – turn on

• OTHER: Keep or turn ON AT alerts for these drugs, based on side effect profile
  o PHENOBARBITAL – keep on
  o BREXIPIPRAZOLE – turn on
  o BUSPIRONE – keep on
  o BUTALBITAL – turn on
  o LITHIUM – keep on
  o LEVORPHANOL – turn on
  o TRAZODONE – keep on
  o MIDAZOLAM – turn on
  o MIRTAZAPINE – keep on
  o NEFAZODONE – turn on
  o PIMOZIDE – keep on
  o SODIUM OXYBATE – turn on

• OTHER: Keep or turn OFF AT alerts for this drug, based on side effect profile
  o BUPROPION – turn off

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:
• Review the decisions made for each of the 32 drugs
• Re-evaluate the testing of the AT alert for at least a 90-day period and present the results at the next DUR Board meeting in September 2017.
• Update the DUR manual and alert profiles, as needed, to reflect any changes in the AT alert.
• Consider DUR educational outreach through a DUR educational bulletin or alert to describe any changes in the AT alert.
Medi-Cal DUR Educational Outreach to Providers: Early Refill Proposal

Background:
The objective of Medi-Cal prospective drug use review (DUR) is to assist pharmacists in screening select drugs for certain clinically important potential drug therapy problems before the prescription is dispensed to the patient, thereby enhancing the clinical quality and cost effective use of those drugs. In accordance with California Board of Pharmacy requirements and federal rules, Medi-Cal prospective DUR includes an alert for overutilization, also known as an early refill (ER) or refill-too-soon. This alert is generated if the most recent previous prescription for the identical product for the same Medi-Cal fee-for-service beneficiary has greater than 25% of the days’ supply remaining. Currently, the ER alert is turned on for every drug.

Early refill alerts are intended to protect patients from adverse events associated with using a prescribed medication beyond the recommended dose. While the Medi-Cal DUR program recognizes that a legitimate need for an early refill may exist in some situations, early refills can also indicate drug overutilization or an increased potential for fraud, abuse, and diversion. Serious consequences of overutilization can include drug overdose, additive toxicity, and increased side effects. Finally, overutilization of certain drugs may serve as an indication of uncontrolled disease.

Early Refill Alerts in the Medi-Cal Fee-for-Service (FFS) Population:
Between October 1, 2015, and September 30, 2016 a total of 1,302,881 ER alerts were generated by pharmacy claims processed in the Medi-Cal fee-for-service program. Of these, a total of 397,848 (30.5%) were overridden by providers at the point-of-service, resulting in a paid claim. A review of the ER alert data by pharmacy showed that the vast majority of pharmacies use the ER alert sparingly. Out of 5,342 pharmacies with a paid claim for a Medi-Cal fee-for-service beneficiary during FFY 2015, the top 100 pharmacies by total ER overrides were responsible for 29.4% of the ER overrides and only 18.4% of paid pharmacy claims.

The top 20 drugs by total ER alert overrides during this time period (FFY 2015) are shown in Table 1, along with the total number of paid claims for each drug during FFY 2015. While not shown among the top 20 drugs, a total of 17,683 scheduled (schedule II through V) medications (4.4%) had ER alert overrides.
Table 1. Top 20 Drugs by Total Early Refill (ER) Alert Overrides during FFY 2015.

<table>
<thead>
<tr>
<th>Rank by Total ER Alerts</th>
<th>Drug</th>
<th>Total Alerts</th>
<th>Total Paid Claims</th>
<th>% of Paid Claims w/ER Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QUETIAPINE FUMARATE</td>
<td>38,500</td>
<td>546,307</td>
<td>7.0%</td>
</tr>
<tr>
<td>2</td>
<td>ARIPIPRAZOLE</td>
<td>29,303</td>
<td>409,451</td>
<td>7.2%</td>
</tr>
<tr>
<td>3</td>
<td>RISPERIDONE</td>
<td>21,501</td>
<td>357,966</td>
<td>6.0%</td>
</tr>
<tr>
<td>4</td>
<td>OLANZAPINE</td>
<td>19,982</td>
<td>289,479</td>
<td>6.9%</td>
</tr>
<tr>
<td>5</td>
<td>BENZTROPINE MESYLATE</td>
<td>16,605</td>
<td>232,698</td>
<td>7.1%</td>
</tr>
<tr>
<td>6</td>
<td>LITHIUM CARBONATE</td>
<td>10,277</td>
<td>118,239</td>
<td>8.7%</td>
</tr>
<tr>
<td>7</td>
<td>ASPIRIN</td>
<td>9,686</td>
<td>311,405</td>
<td>3.1%</td>
</tr>
<tr>
<td>8</td>
<td>METFORMIN HCL</td>
<td>8,448</td>
<td>183,230</td>
<td>4.6%</td>
</tr>
<tr>
<td>9</td>
<td>LURASIDONE HCL</td>
<td>7,926</td>
<td>138,574</td>
<td>5.7%</td>
</tr>
<tr>
<td>10</td>
<td>LEVETIRACETAM</td>
<td>7,226</td>
<td>73,891</td>
<td>9.8%</td>
</tr>
<tr>
<td>11</td>
<td>DOCUSATE SODIUM</td>
<td>7,067</td>
<td>223,486</td>
<td>3.2%</td>
</tr>
<tr>
<td>12</td>
<td>LISINOPRIL</td>
<td>6,767</td>
<td>152,102</td>
<td>4.4%</td>
</tr>
<tr>
<td>13</td>
<td>ZIPRASIDONE HCL</td>
<td>6,642</td>
<td>80,938</td>
<td>8.2%</td>
</tr>
<tr>
<td>14</td>
<td>FERROUS SULFATE</td>
<td>6,586</td>
<td>192,664</td>
<td>3.4%</td>
</tr>
<tr>
<td>15</td>
<td>ALBUTEROL SULFATE</td>
<td>6,578</td>
<td>229,776</td>
<td>2.9%</td>
</tr>
<tr>
<td>16</td>
<td>HALOPERIDOL</td>
<td>6,506</td>
<td>87,073</td>
<td>7.5%</td>
</tr>
<tr>
<td>17</td>
<td>LEVOTHYROXINE SODIUM</td>
<td>5,689</td>
<td>122,231</td>
<td>4.6%</td>
</tr>
<tr>
<td>18</td>
<td>GABAPENTIN</td>
<td>5,609</td>
<td>99,415</td>
<td>5.6%</td>
</tr>
<tr>
<td>19</td>
<td>LORATADINE</td>
<td>5,269</td>
<td>210,634</td>
<td>2.5%</td>
</tr>
<tr>
<td>20</td>
<td>DIVALPROEX SODIUM</td>
<td>5,257</td>
<td>56,478</td>
<td>9.3%</td>
</tr>
</tbody>
</table>

**Objectives:**
- To assess the feasibility and acceptability of DUR educational outreach letters to pharmacies
- To decrease the total volume of early refill overrides by pharmacies

**Methods:**
An evaluation will be done to identify the top 100 pharmacies by total number of ER alert overrides in the Medi-Cal fee-for-service program during calendar year 2016 (between January 1, 2016, and December 31, 2016). Pharmacies among the top 100 pharmacies by total number of ER alert overrides will be sent a letter (Appendix A) with more information about early refills. The mailing will also include the following:
- Provider ranking by number of ER alert overrides (overall and scheduled medications)
- Pharmacy response survey (Appendix B) for each provider

**Outcomes:**
The primary outcome variable will be the percentage decrease in the number of ER alert overrides among all pharmacies who received the mailing, assessed one year after the DUR mailing. This percentage will be compared with the percentage decrease in the number of ER alert overrides among all pharmacies not receiving the DUR mailing.

In addition, response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.
Appendix A. Letter to Pharmacies.

May XX, 2017
<<PROVIDER>>
<<PROVIDER ADDRESS 1>>, <<PROVIDER ADDRESS 2>>
<<PROVIDER CITY>>, <<PROVIDER STATE>> <<PROVIDER ZIP>>

RE: Prospective Drug Utilization Review Early Refill Initiative

Dear Provider,

The objective of Medi-Cal prospective drug use review (DUR) is to assist pharmacists in screening select drugs for certain clinically important potential drug therapy problems before the prescription is dispensed to the patient, thereby enhancing the clinical quality and cost effective use of those drugs.

In accordance with California Board of Pharmacy requirements and federal rules, Medi-Cal prospective DUR includes an alert for overutilization, also known as an early refill (ER) or refill-too-soon. This alert is generated if the most recent previous prescription for the identical product for the same Medi-Cal fee-for-service beneficiary has greater than 25% of the days’ supply remaining.

For your reference, you are receiving this letter because your pharmacy ranked as one of the top 100 pharmacies in California with the greatest number of overrides to the early refill (ER) alert in 2016.

**Total Early Refill Alert Overrides in 2016:**
- All Drugs: XX,XXX overrides (rank: #X)
- Scheduled Drugs: XXX overrides (rank: #X)

While the Medi-Cal DUR program recognizes that a legitimate need for an early refill may exist in some situations, early refills can also indicate drug overutilization or an increased potential for fraud, abuse, and diversion. Persistent high volumes of early refill alert overrides may result in a reexamination of current early refill policy.

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 Hannah Orozco, DUR Pharmacist, at (916) 936-7227.

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. Pharmacy Response Survey.

PHARMACY RESPONSE SURVEY

What did you think of the enclosed information provided on early refills? (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

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

☐ Pharmacy-specific utilization profiles
☐ Pharmacy-specific prospective DUR alert summaries
☐ Other (please specify):

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

Would you like more information about early refills or other prospective DUR alerts?

☐ No
☐ Yes, I will contact the DUR Pharmacist at (916) 936-7227
☐ Yes, please contact me at the following telephone number:

______________________________________________________________________________

Additional comments or suggestions:

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

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.
Background:
Fluoroquinolones, including ciprofloxacin, ofloxacin, gemifloxacin, levofloxacin, and moxifloxacin, are broad-spectrum antibiotics that interfere with the growth of bacteria via inhibition of certain enzymes needed for bacterial replication. Fluoroquinolones are FDA-approved to treat various bacterial infections and are the only oral antibiotics that can be reliably used to treat infections caused by gram-negative bacilli, including strains of antibiotic resistant bacteria.

Despite the many FDA-approved indications for use of fluoroquinolones, the Centers for Disease Control and Prevention, the Infectious Diseases Society of America, and the American Thoracic Society all recommend fluoroquinolones not be used as first-line therapy in community settings when other treatment options are available. Fluoroquinolones should be initiated only after other antibiotic classes have been tried and failed, or in such cases with a demonstrated drug resistance.

On July 26, 2016, the FDA approved safety labeling changes for fluoroquinolones, including an updated Boxed Warning, due to potential serious adverse effects related to use of fluoroquinolones, including tendinitis, tendon rupture, peripheral neuropathy, confusion, and hallucinations. The FDA recommends that fluoroquinolones should not be prescribed to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections, as the risks outweigh the benefits.

Early Refill Alerts in the Medi-Cal Fee-for-Service (FFS) Population:
A total of 50,843 community-dwelling Medi-Cal fee-for-service beneficiaries had at least one paid claim for a fluoroquinolone between December 1, 2015, and November 30, 2016, and at least one primary or secondary ICD-10-CM diagnosis code within the seven days prior. There were 1,567 beneficiaries excluded from the study population (3%) as
they were identified as having a history of penicillin or other drug allergy that would impact the use of fluoroquinolones as a first-line therapy, leaving a total of 49,276 beneficiaries in the study population.

Approximately two-thirds (n = 33,483; 68%) of fluoroquinolone use during the measurement year appeared to be potentially inappropriate based on the new FDA recommendations, with 5,102 beneficiaries (10%) having a primary or secondary diagnosis of acute bacterial exacerbation of chronic bronchitis, a total of 9,165 beneficiaries (19%) with acute sinusitis, and 19,306 beneficiaries (39%) with an uncomplicated UTI. For reference, uncomplicated UTI was the most frequent diagnosis given preceding a paid claim for a fluoroquinolone, followed by septicemia.

**Objectives:**
- To inform providers of the FDA-approved safety labeling changes for fluoroquinolones
- To decrease the number of Medi-Cal patients receiving treatment with fluoroquinolones for acute bacterial exacerbation of chronic bronchitis, acute sinusitis, and uncomplicated UTI

**Methods:**
An evaluation will be done to identify the top 100 prescribers (by total paid claims) of fluoroquinolones in the Medi-Cal fee-for-service program during 2016. Providers who are among the top prescribers of fluoroquinolones will be sent a letter (Appendix A) with more information about the FDA recommendations for fluoroquinolone use. The mailing will also include the following:
- Provider’s ranking (by total paid claims) of fluoroquinolone prescribing in the Medi-Cal fee-for-service population
- Medi-Cal DUR article on fluoroquinolones
- Provider response survey (Appendix B) for each provider

**Outcomes:**
The primary outcome variable will be the percentage decrease in the number of paid claims for fluoroquinolone among prescribers who received the mailing, assessed one year after the DUR mailing. This percentage will be compared with the percentage decrease in the number of ER alert overrides among all prescribers not receiving the DUR mailing.

In addition, response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.
Appendix A. Letter to Prescribers.

May XX, 2017

<<PROVIDER>>
<<PROVIDER ADDRESS 1>>, <<PROVIDER ADDRESS 2>>
<<PROVIDER CITY>>, <<PROVIDER STATE>> <<PROVIDER ZIP>>

RE: Retrospective Drug Utilization Review Fluoroquinolone Initiative

Dear Provider,

Despite the many FDA-approved indications for use of fluoroquinolones, the Centers for Disease Control and Prevention, the Infectious Diseases Society of America, and the American Thoracic Society all recommend fluoroquinolones not be used as first-line therapy in community settings when other treatment options are available. Fluoroquinolones should be initiated only after other antibiotic classes have been tried and failed, or in such cases with a demonstrated drug resistance.

On July 26, 2016, the FDA approved safety labeling changes for fluoroquinolones, including an updated *Boxed Warning*, due to potential serious adverse effects related to use of fluoroquinolones, including tendinitis, tendon rupture, peripheral neuropathy, confusion, and hallucinations. The FDA recommends that fluoroquinolones should not be prescribed to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections, as the risks outweigh the benefits.

Using the new FDA recommendations as a guide, a recent analysis by the Medi-Cal Drug Use Review (DUR) program found that between December 1, 2015, and November 30, 2016, approximately 68% of fluoroquinolone use in the Medi-Cal fee-for-service program was for a potentially inappropriate indication. The full publication is included with this mailing for your review and can be found on the Medi-Cal DUR website at: https://files.medi-cal.ca.gov/pubsdoco/dur/Articles/dured_25667.pdf.

For your reference, you are receiving this letter because you were one of the top 100 prescribers (by total quantity prescribed) of fluoroquinolones in the Medi-Cal fee-for-service program during 2016.
Fluoroquinolone use contributes to the proliferation of antibiotic-resistant bacteria and may result in disabling and potentially permanent side effects. Community-based treatment with fluoroquinolones should be initiated only after other antibiotic classes have been tried and failed, or in such cases with a demonstrated drug-resistance. Limiting the use of fluoroquinolones to those patients where the benefits clearly outweigh the potential risks can lead to improved patient outcomes and a reduction in adverse events.

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 Hannah Orozco, DUR Pharmacist, at (916) 936-7227.

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
PROVIDER RESPONSE SURVEY

What did you think of the enclosed information provided on fluoroquinolones? (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

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):

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Additional comments or suggestions:

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Thank you for participating in the Medi-Cal Drug Use Review Program.

Please return within 30 days of receipt using the enclosed self-addressed stamped envelope.
DATES OF REVIEW: April 25, 2017

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:
- All over-the-counter drugs on the Medi-Cal List of Contract Drugs were included in this review.

DRUG PROBLEM TYPES: Over Utilization (OU), Therapeutic Appropriateness (O1)

BACKGROUND: The outpatient prescription drug coverage for the Medi-Cal fee-for-service program includes all federally required drug classes and optional drug classes like vitamins and over-the-counter (OTC) medications when prescribed by a physician. OTC medications on the Medi-Cal List of Contract Drugs do not generally require an approved Treatment Authorization Request (TAR), unless there are other restrictions to use. On March 24, 2011, legislation was passed in California eliminating OTC cough and cold products as a covered pharmacy benefit. As a result of this legislation, effective March 1, 2012, OTC cough and cold products are not a benefit of the Medi-Cal program. All OTC antihistamines, all OTC decongestants and all OTC antihistamine/decongestant combination drug products are restricted to individuals 2 years of age and older, based on current Federal Drug Administration (FDA) recommendations.

ISSUES: Several OTC medications frequently rank among the top drugs by total number of utilizing beneficiaries. Periodic reviews of utilization patterns for these drugs should be conducted to evaluate potential drug problems.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: Paid claims for all OTC medications with dates of service between January 1, 2016 and December 31, 2016 were reviewed for Medi-Cal fee-for-service beneficiaries. A review of the top 10 OTC drugs by utilizing beneficiaries overall is shown in Table 1, and by each age group in Table 2. In 2016, there were a total of 1,686,513 paid claims for OTC drugs, with an average reimbursement paid to pharmacies of $16.23 per claim.

Table 1. Top 10 OTC drugs by total utilizing beneficiaries in 2016.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total Utilizing Beneficiaries</th>
<th>Total Paid Claims</th>
<th>Total Reimbursement Paid to Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>FERROUS SULFATE</td>
<td>106,616</td>
<td>188,323</td>
<td>$2,182,017</td>
</tr>
<tr>
<td>DOCUSATE SODIUM</td>
<td>104,462</td>
<td>221,058</td>
<td>$1,997,750</td>
</tr>
<tr>
<td>ACETAMINOPHEN</td>
<td>94,135</td>
<td>115,304</td>
<td>$826,663</td>
</tr>
<tr>
<td>ASPIRIN</td>
<td>94,077</td>
<td>307,521</td>
<td>$2,263,099</td>
</tr>
<tr>
<td>LORATIDINE</td>
<td>90,025</td>
<td>208,643</td>
<td>$2,191,959</td>
</tr>
<tr>
<td>HYDROCORTISONE</td>
<td>52,396</td>
<td>67,802</td>
<td>$1,206,138</td>
</tr>
<tr>
<td>FOLIC ACID</td>
<td>50,150</td>
<td>141,393</td>
<td>$1,060,260</td>
</tr>
<tr>
<td>PRENATAL VIT#96/FERROUS FUM/FA</td>
<td>49,538</td>
<td>69,624</td>
<td>$631,255</td>
</tr>
<tr>
<td>DIPHENHYDRAMINE HCL</td>
<td>44,833</td>
<td>88,335</td>
<td>$813,342</td>
</tr>
<tr>
<td>CLOTRIMAZOLE</td>
<td>38,425</td>
<td>50,623</td>
<td>$1,398,203</td>
</tr>
<tr>
<td>Age Group</td>
<td>Drug</td>
<td>Total Utilizing Beneficiaries</td>
<td>Total Paid Claims</td>
</tr>
<tr>
<td>-----------</td>
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<tr>
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<td>ELECTROLYTES/DEXTROSE</td>
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<td>5,611</td>
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<td>LORATADINE</td>
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<td>PERMETHRIN</td>
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<td>FOLIC ACID</td>
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<td>DOCUSATE SODIUM</td>
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<td>ACETAMINOPHEN</td>
<td>8,539</td>
<td>9,585</td>
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## Table 1 (cont.). Top 10 OTC drugs by total utilizing beneficiaries in each age group in 2016.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Drug</th>
<th>Total Utilizing Beneficiaries</th>
<th>Total Paid Claims</th>
<th>Most Frequent Day Supply per Claim</th>
<th>Most Frequent Quantity per Claim</th>
<th>Total Reimbursement Paid to Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-64</td>
<td>ASPIRIN</td>
<td>43,892</td>
<td>94,367</td>
<td>30 days</td>
<td>60 tablets</td>
<td>$656,064</td>
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<tr>
<td></td>
<td>LORATADINE</td>
<td>31,752</td>
<td>67,186</td>
<td>30 days</td>
<td>30 tablets</td>
<td>$675,628</td>
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<td>DOCUSATE SODIUM</td>
<td>30,455</td>
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<td>30 days</td>
<td>30 tablets</td>
<td>$612,729</td>
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<td>FERROUS SULFATE</td>
<td>18,191</td>
<td>35,418</td>
<td>30 days</td>
<td>60 tablets</td>
<td>$366,591</td>
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<td>OMEPRAZOLE MAGNESIUM*</td>
<td>6,280</td>
<td>8,347</td>
<td>30 days</td>
<td>28 tablets</td>
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<td>65+</td>
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<td>60 tablets</td>
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<td>LORATADINE</td>
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<td>30 tablets</td>
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<td>FERROUS SULFATE</td>
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<td>CALCIUM CARBONATE</td>
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<td>CALCIUM PHOSPHATE DIBAS/VIT D3</td>
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<td></td>
<td>CLOTRIMAZOLE</td>
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<td>6,992</td>
<td>30 days</td>
<td>45 g</td>
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<td>3,787</td>
<td>7,876</td>
<td>30 days</td>
<td>60 tablets</td>
<td>$69,828</td>
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</table>

*Restricted to claims with dates of service through April 30, 2016.

FERROUS SULFATE, LORATIDINE, and CLOTRIMAZOLE appeared in the top 10 drugs across all age groups.

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

- Review the utilization data for OTC medications to determine if there is a need for further evaluation of any of these drugs as part of a retrospective DUR review.
- Review the utilization data for OTC medications to determine if there is a need for further evaluation of any of these drugs as part of DUR educational outreach to providers.
- Consider educational outreach to providers to increase the quantity per paid claim on prescriptions for OTC chronic medications.
- Discuss whether OTC drugs should be included in a rotation as part of regular reviews. If so, discuss the preferred method of review:
  - A biennial review of the entire class of OTC drugs
  - An annual review of a selected OTC drug or drug class
Update: DUR Publications

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

May 16, 2017
DUR Publications

April 2017: DUR Educational Alert

- Medi-Cal Expands Access to Adult Immunizations in Pharmacies

April 2017: DUR Educational Bulletin

- Improving the Quality of Care: Overutilization of Proton Pump Inhibitors
April 2017: DUR Educational Alert (1)

Medi-Cal Expands Access to Adult Immunizations in Pharmacies

- The Medi-Cal fee-for-service list of contract drugs now includes all ACIP-recommended adult immunizations as a pharmacy benefit
- Medi-Cal managed care plans will have to offer these adult immunizations on their pharmacy formulary as well
- Presumptive Eligibility for Pregnant Women (PE4PW) program has also been expanded to offer a full range of influenza vaccines, in addition to Tdap
- New pharmacy regulations require that pharmacists notify providers and submit vaccination information to the California Immunization Registry (CAIR)
April 2017: DUR Educational Bulletin (1)

Overutilization of Proton Pump Inhibitors

- Learning Objectives
  - Review the appropriate indications for short-term and long-term use of proton pump inhibitors (PPIs)
  - Describe potential adverse effects associated with use of PPIs
  - Summarize best practices for responsible prescribing of PPIs
April 2017: DUR Educational Bulletin (2)

Overutilization of Proton Pump Inhibitors

- Background
  - Proton pump inhibitors (PPIs), typically used to reduce gastric acid, are one of the most commonly prescribed medications in the United States.
    - An estimated 25% to 70% of these prescriptions have no appropriate indication for PPIs
    - Treatment with PPIs often continues well beyond recommended guidelines
    - Increasing data showing PPIs are associated with a number of adverse effects
April 2017: DUR Educational Bulletin (3)

Overutilization of Proton Pump Inhibitors

- Background (continued)

  - The FDA has issued several safety alerts for PPIs and adverse effects may include increased risk of both acute and chronic kidney disease, hypomagnesemia, *Clostridium difficile* infection, osteoporotic fractures, and dementia.

  - Indications for PPI therapy include:
    - Short-term: GERD, gastric and duodenal ulcers, *Helicobacter pylori* infection, stress ulcer prophylaxis
    - Long-term: refractory GERD, erosive esophagitis, Zollinger-Ellison Syndrome, NSAID-induced ulcers, chronic anticoagulation after a GI bleed, Barrett’s esophagus
April 2017: DUR Educational Bulletin (4)

Overutilization of Proton Pump Inhibitors

- Methods
  - Retrospective cohort study using pharmacy and medical claims data
  - Study population inclusion criteria:
    - At least one paid pharmacy claim for a PPI between November 1, 2015 and October 31, 2016
    - Continuous eligibility in the Medi-Cal fee-for-service population
  - Long-term use determined when paid claims for PPIs totaled > 300 treatment days during the measurement year
April 2017: DUR Educational Bulletin (5)

Overutilization of Proton Pump Inhibitors

Use of PPIs in the Medi-Cal Fee-for-Service Population

- A total of 23,921 continuously-eligible beneficiaries had least one paid pharmacy claim for a PPI during the measurement year
  - 68% had ≤ 3 paid claims for PPIs and 61% had a PPI treatment duration of ≤ 90 days
  - Long-term users made up 13.0% of the study population (n = 2,995 beneficiaries)
- The majority (77%) did not have an appropriate indication for either short-term or long-term PPI therapy
April 2017: DUR Educational Bulletin (6)

Overutilization of Proton Pump Inhibitors

- Concomitant use of medications
  - No difference between those beneficiaries with or without an appropriate indication for use of PPIs in the concomitant use of medications that may increase the risk of adverse events with long-term or high-dose PPI therapy
  - Beneficiaries with potentially appropriate indications for use of PPI therapy were more likely to have concomitant use of H2-receptor inhibitors, metoclopramide, and antacids
April 2017: DUR Educational Bulletin (7)

Overutilization of Proton Pump Inhibitors

- Clinical Recommendations
  - Prescribe PPIs only for clearly documented indications and reevaluate indications at transitions of care
  - Exercise caution in the elderly and patients with other risk factors for *C. difficile* infection or bone fractures
  - Recommend antacids or H2-blockers as needed for breakthrough symptoms after PPI discontinuation
  - Encourage non-pharmacologic/lifestyle management as first-line for GERD symptoms
  - For patients requiring long-term PPI therapy, obtain baseline magnesium level and follow recommended monitoring guidelines
Future Topics: Bulletins

DUR Educational Bulletins:

- Summarize relative risk of QT interval prolongation due to adverse drug reactions (Submitted for publication, May 2017)

- Describe recent FDA labeling changes for opioids and other CNS depressants, including an evaluation of high-risk drug use in the Medi-Cal population (in progress)

- 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

- Topic from today’s meeting: Anything within the biennial report?
Future Topics: Outreach/Provider Letters

DUR Educational Outreach to Medi-Cal Providers:

- Asthma Letters: Re-mailing of returned mail from February mailing (completed April 2017)
- Topic from today’s meeting: Early Refill
- Topic from today’s meeting: Fluoroquinolones
- Topic from today’s meeting: Anything within the biennial report?
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 (ongoing)

Prospective DUR Reviews:

- Top DUR alerts by volume (ongoing)
- Annual review of categories for duplicate therapy (Section 25, ongoing)
- Discrepancy clean-up (Section 20, ongoing)
- Quarterly review of new GCNs (ongoing, quarterly)
- Updated therapeutic duplication alert, once implemented
- Review of test data: additive toxicity alert (for presentation in September 2017)
Future Topics: Retrospective Reviews

Retrospective DUR Reviews:

- Hormonal contraceptives, specifically in the pharmacy setting
- Assessment of opioid use and mortality, linking death index information with medical/pharmacy claims data (stratified by gender)
- 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)

Topic from today’s meeting: Anything within the biennial report?
Medi-Cal Drug Utilization Review Board Meeting
Pharmacy Updates

Pauline Chan, R.Ph., MBA
Pharmacy Policy Branch
5-16-17
Topics

- Medicaid DUR State Comparison for FFY 2015 – Best Practices from other states
- Pharmacy Policy Change: Meperidine
- Pharmacy Policy Change: Opioid Quantity Limits
- MMWR: Initial Prescription Opioids and Long Term Opioid Use
- FDA Drug Safety Communications: Codeine & Tramadol
- DHCS Strategy for Quality Improvement in Health Care, 2017
- Academic Detailing Conference, October 12, 2017
- Academic Detailing Resources
Medicaid DUR State Comparison for FFY 2015

• state comparison report 2015

• Highlights from the Medicaid Drug Utilization Review State Comparison/Summary FFY 2015 Annual Report
  – How California compares with the rest of the country’s state Medicaid agencies
  – Best practices from other states

• Applying States’ Best Practice to Fee-For-Service Medi-Cal DUR Program (attached)
  – Topics
  – Timeline
Meperidine

• Pharmacy Policy Change:
  – Effective May 1, 2017, all meperidine formulations require treatment authorization request (TAR)
Opioids Quantity Limits

• Pharmacy Policy Change: Effective July 1, 2017
  – Opioids quantity limit for short-acting long-acting opioids
    • Set number of units/day
    • Set number of days supply
    • Limited to refills every 25 days x 3
Opioids Long Term Use

- **MMWR Opioids**
- Morbidity and Mortality Weekly Report, March 17, 2017
- In a representative sample of opioid naïve, cancer-free adults who received a prescription for opioid, the likelihood of chronic opioid use increased with each additional day of medication supplied starting with the third day.
Opioids Long Term Use -2

• Findings:
  – *Sharpest increases* observed:
    • After the 5\textsuperscript{th} and 31\textsuperscript{st} day use
    • A second prescription or refill
    • 700 mg morphine milligram equivalent cumulative dose
    • Initial 10-30 days supply
  – *Highest likelihood* of continued opioid use at 1 and 3 years:
    • Started on a long-acting opioids
    • Started on tramadol
• Implications: awareness, early discussion of long term use
• **Codeine and tramadol**
  
  FDA is restricting the use of codeine and tramadol use in children
  – codeine and tramadol are *contraindicated* in use to treat cough or pain for children <12 years of age
  – tramadol is *contraindicated* in children <18 years to treat pain after surgery to remove the tonsils and/or adenoids
  – *warning* (recommends against) use of codeine and tramadol in adolescents 12-18 years of age who are obese, has obstructive sleep apnea or severe lung disease, with increased risk of serious breathing problems

• FDA issues warning (recommends against) use in women breastfeeding
DHCS Quality Strategy Report

- Released annually
- Includes progress and status of QIPs
- Organized by the 7 priorities
- Organized by divisions and programs
- DUR to submit a project for continuous tracking and trending
• DHCS Strategy for Quality Improvement in Health Care

DHCS Quality

 Medi-Cal DUR Board Meeting 05-16-17
DHCS Quality Strategy Report -3

• Priority 7: Eliminate Health Disparities
  Fact sheets

• Looking to the Future- Programs and Policies in Development
  – Emerging areas important to population health
  – Dialogue with stakeholders to form partnerships

Medi-Cal DUR Board Meeting 05-16-17
Academic Detailing

• Webpage:
  – academic detailing
  – Additional resources (attached)
• 2017 Conference Date: October 12, 2017
  – Speakers
  – Topics
  – Best Practices
  – Pilot
Questions?

Email:
Pauline.Chan@dhcs.ca.gov
Applying States’ Best Practice to Improve Fee-For-Service Medi-Cal Drug Utilization Review Program: FFY 2017 & 2018

April 2017

The DUR board, at the February 2017 board meeting, reviewed the document “Highlights from the Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report”. Based on this document, Medi-Cal identifies a number of opportunities for improvement. The following lists the improvement topics and the proposed timeline.

I. Prospective DUR
   A. General
      • Initiate follow up actions with individual pharmacy providers who routinely override prospective alerts. Possible action may include sending letters to the pharmacy providers with the highest overrides. Timeline: FFY 2017

   B. Early Refills
      • Evaluate early refills policy by therapeutic class and consider setting specific limitations by each class of drugs: For example, proton pump inhibitors, skeletal muscle relaxants. Timeline: FFY 2018.

   C. Top 10 Claims Data
      • The current Fee-For-Service (FFS) top 10 claims data includes all carved out drugs claims, which includes both FFS and managed care populations, resulting in FFS top 10 claims data to almost exclusively from the carved out drugs. Excluding carved out drugs and counting claims from FFS population only, may offer additional and important insights to FFS drug utilizations. Timeline: FFY 2018

VIII. Fraud, Waste, and Abuse Detection
   A. Lock-In or Patient Review and Restrictive Programs
      General
      • Invite Audit & Investigational Branch (IB) to present a summary of lock in program at future DUR board meeting. Timeline: FFY 2017

      Prescription Drug Monitoring Program (PDMP)
      • Review “Integrating and Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States”. Center for Disease Control publication, February 2017 PDMP
FEE-FOR-SERVICE MEDI-CAL DRUG UTILIZATION REVIEW PROGRAM

**Opioids**

*Short-acting*
- Policy change: Point-of-Service (POS) edits to limit the quantity of short-acting opioids by restricting refill to a maximum of 30 days of supply (refill allowable at day 25). Timeline: July 1, 2017

*Long-acting*
- Policy change: Point-of-Service (POS) edits to limit the quantity of short-acting opioids by restricting refill to a maximum of 30 days of supply (refill allowable at day 25). Timeline: July 1, 2017

**Concurrent use of opioids and benzodiazepines**
- California performed a retrospective DUR study in FFY 2016. This study is currently in review. Future work to include a follow up action plan. Timeline: FFY 2017

B. Morphine Equivalent Daily Dose (MEDD)
- Coordinate with State-wide Opioid Workgroup to determine MEDD cut off dose, and to develop an algorithm to calculate MEDD. Timeline: FFY 2018

C. Buprenorphine and Buprenorphine/Naloxone Combinations
- Explore the feasibility to have Prospective DUR edits in place to monitor opioids being used concurrently with any buprenorphine drug. Timeline: FFY 2018

D. Antipsychotics/Stimulants

  *Antipsychotics*
  - Medi-Cal DUR has joined a CMS-led affinity group to address antipsychotic drug use in children. The affinity group is extended to FFY 2018 with continuous tracking of progress. Timeline: FFY 2017-2018.

XI. Managed Care Organizations (MCOs)
- Implement the new Medicaid Managed Care regulations relevant to the Medi-Cal DUR program. Timeline: FFY 2018.
I. Choosing Wisely

www.choosingwisely.org

Background:
“Choosing Wisely” was launched in 2012 by the American Board of Internal Medicine (ABIM) Foundation and Consumer Reports as a response to Health Care Reform. See article by Howard Brody, MD, PhD. “Medicine’s Ethical Responsibility for Health Care Reform – The Top Five List”, NEJM 362; 4 January 28, 2010. In this article, Dr. Brody advocates that the medical community must address reducing health care cost by reducing waste, if the goal is to provide health coverage to more people. He believes the runaway health cost threatens the success of the health care reform unless we do something about it.

Choosing Wisely encourages consumers to ask their doctors 5 questions before getting any test, treatment or procedures:

1) Do I really need this test or procedure?
2) What are the risks and side effects?
3) Are there simpler, safer options?
4) What happens if I don’t do anything?
5) How much does it cost, and will my insurance pay for it?

Since 2012, Choosing Wisely has partnered with numerous professional organizations, including American Society of Health System Pharmacists (ASHP). The most recent “facts and figures” published by “Choosing Wisely” shows this initiative has made impact in several areas:

1) Engaging clinicians and patients
2) Changing awareness and attitudes
3) Increasing conversations about overuse

The initiative tracks social media engagements and impact. In 2016, it recorded millions of impressions and thousands of tweets and participants. There are active campaigns in many parts of the world, including US and Canada, Brazil, Western Europe, India, Australia and New Zealand.

Why is this important?
1) “Choosing Wisely” lists are evidence-based recommendations created by national medical specialty societies. These lists address safety (free from harm), and avoid duplications of therapy/treatments and make recommendations that are truly necessity.
There is a wide range of topics covered, including antibiotic use, asthma, diabetes, and other chronic conditions to name a few. Pharmacists can play a pivotal role to engage consumers and clinicians in these conversations.

2) “Choosing Wisely” actively engages consumers and the public, which aligns with DHCS quality strategy.

II. National Resource Center for Academic Detailing (NaRCAD)

www.narcad.org

Background:

NaRCAD was found in 2010 and is operating within Brigham & Women’s Division of Pharmacoepidemiology & Pharmacoeconomics (DoPE).

Academic Detailing (AD) is a technique used in educational outreach to clinicians. It brings evidence-based care information to providers with up-to-date clinical information delivered by peers in an engaging format. According to the NaRCAD website, a successful AD visit is “highly interactive, always a dialogue, and continuously assesses a clinician’s individual needs in order to promote better prescribing, screening and patient education”.

Pharmacists are ideally suited as an academic detailer to discuss appropriate medication use with clinicians.

NaRCAD offers training opportunities that uses small groups, and emphasizes hands on training. This includes role play and a good understanding of behavioral sciences. The goal is to enable the Academic Detailer to engage the clinician/prescriber in a meaningful and engaging manner.

The website has numerous resources with evidence-based care information that is written in a format that maximize clinician engagement. These are helpful to programs to get off the ground by having “ready to use” materials that require minimal tweaking.

Why is this topic important?

Pharmacists are well-trained as drug information experts, but not necessarily well-trained in delivering the clinical information. Academic Detailing training bridges the gap by enhancing pharmacist’s skills in bringing evidenced-based information to other providers (typically a physician) in an engaging format. Studies have shown Academic Detailing results in better
outcome in enabling physicians to prescribe based on evidenced, instead of to prescribe based on individual’s own experience.

Combing “Choosing Wisely” and Academic Detailing

The following link to the article is an example from Yale University Medical Center Department of Emergency Medicine. The article shows how coupling the use of academic detailing technique and evidence-base recommendation from “Choosing Wisely” could forge a better outcome to reduce unneeded tests. example

Using similar techniques, pharmacists can apply evidence-based information (knowledge) with academic detailing technique (delivery skills) where pharmacists are part of a care team.