California
Medicaid Fee-For-Service (FFS)
2019 Drug Utilization Review (DUR)

DEF-MDL-15357.00001

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California DUR 2019 FFS Individual State Report

Section I – Number of Beneficiaries

Question	Response
1. On average, how many of your state's Medicaid beneficiaries are enrolled in your state's Medicaid Fee-For-Service (FFS) program that have a pharmacy benefit?	**2,294,983**
2. On average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)?	**10,559,452**

Section II - Prospective DUR (ProDUR)

Question	Response
1. Indicate the type of your pharmacy point of service (POS) vendor.	**Contractor**
a. Vendor Name	**Conduent**
b. If not state-operated, is the POS vendor also the MMIS fiscal agent or a separate PBM?	**POS vendor is the fiscal agent**
2. Identify ProDUR criteria source.	**First Databank**
If "Other," please specify	N/A
3. Are new ProDUR criteria approved by the DUR Board?	**No**
If "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 level-one ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service and resolution)?	**Yes**
If "varies," please explain	N/A
5. Do you receive and review follow-up reports providing individual pharmacy provider DUR alert override activity in summary and/or in detail?	**Yes**
a. If "Yes," how often do you receive reports?	**Annually, Ad hoc (on request)**

Question	Response
If "Other," please explain	N/A
b. If you receive reports, do you follow up with those providers who routinely override with interventions?	**Yes**
If "Yes," by what method do you follow up?	Contact Pharmacy
If "Other," please explain.	N/A
If "No," please explain	N/A
If "No," please explain	N/A
6. Early Refill	
a. At what percent threshold do you set your system to edit?	
i) Non-controlled drugs:	**75%**
ii) Schedule II controlled drugs:	**75%**
iii) Schedule III through V controlled drugs:	**75%**
b. For non-controlled drugs: When an early refill message occurs, does the state require prior authorization?	**No**
If "Yes" or "Dependent on medication or situation," who obtains authorization?	N/A
If "No," can the pharmacist override at the point of service?	Yes
c. For controlled drugs: When an early refill message occurs, does the state require prior authorization?	**No**
If "Yes," who obtains authorization?	N/A
If "No," can the pharmacist override at the point of service?	Yes
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**
b. Vacation	**Yes**
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?	**No**
If "Yes," please explain your edit.	N/A
If "No," do you plan to implement this edit?	No

Question	Response
9. Does the state Medicaid agency or the state's Board of Pharmacy have any policy prohibiting the auto-refill process that occurs at the POS (i.e. must obtain beneficiary's consent prior to enrolling in the auto-refill program)?	**No**
10. Does the state Medicaid agency have any policy that provides for the synchronization of prescription refills (i.e. if the patient wants and pharmacy provider permits the patient to obtain non-controlled, chronic medication refills at the same time, the state would allow this to occur to prevent the beneficiary from making multiple trips to the pharmacy within the same month)?	**No**
11. For drugs not on your formulary, does your agency have a documented process (i.e. prior authorization) in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug when medically necessary?	**Yes**
If "Yes," what is the preauthorization process?	The Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug not on the Medi-Cal Fee-for-Service List of Contract Drugs (CDL) with an approved Treatment Authorization Request.
If "No," please explain why there is not a process for the beneficiary to access a covered outpatient drug when it is medically necessary.	N/A
a. Does your program provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation?	**Yes**
If "Yes," what is the process?	The pharmacy may manually bill a 72-hour supply of a covered outpatient prescription drug in an emergency situation.
If "No," please explain.	N/A
12. Please list the requested data in each category in *Table 1 - Top Drug Claims Data Reviewed by the DUR Board* that follows	

Table 1 – Top Drug Claims Data Reviewed by the DUR Board

Top 10 Prior Authorization (PA) Requests by Drug Name	Top 10 Prior Authorization (PA) Requests by Drug Class	Top 5 Claim Denial Reasons Other Than Eligibility (i.e. Quantity Limits, Early Refill, PA, Therapeutic Duplications and Age Edits)	Top 10 Drug Names by Amount Paid	% of Total Spent for Drugs by Amount Paid (From data in Column 4, Determine the % of total drug spend)	Top 10 Drug Names by Claim Count	Drugs by Claim Count % of Total Claims (From data in Column 6, Determine the % of total claims)
aripiprazole	Antipsychotics	age	aripiprazole	10.10%	ibuprofen	2.40%
paliperidone	Analgesics	quantity dispensed exceeds maximum allowed	lurasidone	6.10%	amoxicillin	1.10%
risperidone	Anticonvulsants	exceeds allowable plan days supply	paliperidone	5.40%	albuterol	0.90%
haloperidol	Laxatives	other: Exceeds the 6 prescription limit	other: bictegravir/emtricitabine/tenofovir alafenamide	4.60%	quetiapine	0.90%
quetiapine	Hormones	m/i diagnosis code	elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	3.50%	cephalexin	0.80%
hydrocodone /apap	Other: Stimulants		coagulation factors	3.00%	ferrous sulfate	0.80%
brexipiprazole	Other: Infant formulas		antihemophilic factors	2.90%	aripiprazole	0.80%
olanzapine	Vitamins		abacavir/dolutegravir/lamivudi	2.80%	hydrocodone /apap	0.70%
other: cariprazine	Antidepressants		other: emtricitabine/tenofovir disoproxil fumarate	2.60%	docusate	0.70%
lithium	Other: Anti-alcoholic preparations		antihemophilic factors	1.70%	loratidine	0.70%

Question	Response
13. 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:	**State Board of Pharmacy**
If "Other," please explain:	N/A
14. Summary 1 – Pharmacy Oral Counseling Compliance	**California pharmacy regulations require pharmacies to maintain patient medication**

Question	Response
Summary 1 Pharmacy Oral Counseling Compliance reports the monitoring of pharmacy compliance with all prospective DUR requirements performed by the State Medicaid Agency, the State Board of Pharmacy, or other entity responsible for monitoring pharmacy activities. If the State Medicaid Agency itself monitors compliance with these requirements, it may provide a survey of a random sample of pharmacies with regard to compliance with the Omnibus Budget Reduction Act (OBRA) of 1990 prospective DUR requirement. This report details state efforts to monitor pharmacy compliance with the oral counseling requirement and should describe in detail, utilizing the text box below, the monitoring efforts that were performed and how effective these efforts were in the fiscal year reported.	**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, which compiles annual reports that are available at: https://www.dca.ca.gov/publications/annual_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**

Question	Response
	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 the Centers for Medicare & Medicaid Services, in order 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.**

Section III - RETROSPECTIVE DUR (RetroDUR)

Question	Response
1. Indicate the type of vendor that performed your RetroDUR activities during the time period covered by this report.	**Academic Institution**
a. Identify, by name, your RetroDUR vendor.	**University of California, San Francisco (UCSF)**
b. Is the RetroDUR vendor also the MMIS fiscal agent?	**No**
c. Is the RetroDUR vendor also the developer/supplier of your retrospective DUR criteria?	**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. Who reviews and approves the RetroDUR criteria?	**Other**
"Other," 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.

3. **Summary 2 – Retrospective DUR Educational Outreach** Summary 2 Retrospective DUR Educational Outreach is a year-end summary report on RetroDUR screening and educational interventions. The year-end summary should be limited to the most prominent 10 problems with the largest number of exceptions. The results of RetroDUR screening and interventions should be included and detailed.	**1. Additive toxicity (AT) alert provider letter sent January 2019 - The objectives were 1) to identify beneficiaries at high-risk for adverse events associated with the use of certain opioid medications in combination with benzodiazepines and other CNS depressants; and 2) to help inform health care providers and patients of the serious risks attributed to co-prescribing of opioids with CNS depressants, including benzodiazepines, non-benzodiazepine receptor agonists, and antipsychotics. The study population included 31 beneficiaries who were continuously eligible in the Medi-Cal fee-for-service program between October 1, 2018, and January 31, 2019. Each beneficiary generated an AT alert with pharmacist override during December 2018 and had at least one paid claim for both an opioid and a benzodiazepine, as well as paid claims for at least two additional CNS depressants between October 1, 2018, and December 31, 2018. Those with claims with practice locations including SNF, ICF, home health, and hospice, and diagnostic codes indicating palliative care or cancer treatment were excluded. A total of 67 prescribers were identified for educational outreach letters, which were mailed on January 18, 2019. Any paid claims for gabapentin during the same time period were also included on patient profiles.** **2. Alert: New Naloxone Regulations Effective on January 1, 2019 educational alert published January 2019 - This alert reviewed California Assembly Bill 2760 (Wood, Chapter 324) that was signed into law in 2018 and became effective on January 1, 2019. AB 2760 requires California prescribers to offer a prescription to a patient for either naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid-induced respiratory depression, as a rescue medication under certain conditions.** **3. Clinical Review Update: Morphine Equivalent Daily Dose** **a. Educational bulletin published**

	February 2019 - This bulletin reviewed the morphine equivalent daily dose (MEDD) and how it is being used to indicate potential dose-related risk for prescription opioid overdose. This article also summarized best practices for prescribing opioids, identified resources available that promote responsible opioid prescribing, and described recent state legislation related to prescription opioids. b. Provider letter sent April 2019 - The objective was to educate providers about morphine equivalent daily dose (MEDD) thresholds and updated legislation regarding prescribing opioids in California. The study population included 87 Medi-Cal fee-for-service beneficiaries with at least 1 paid claim > 120 mg MEDD since January 1, 2019. A total of 85 prescribers were identified for educational outreach letters, which were mailed on April 26, 2019. Each letter included patient profiles, the updated Medi-Cal DUR MEDD article, a naloxone handout, and provider response surveys. 4. Drug Safety Communication: Updated Adverse Effects from Fluoroquinolone Antibiotics educational alert published March 2019 - This alert summarized an FDA warning based on epidemiological studies and cases from the FDA Adverse Event Reporting System (FAERS) database that found fluoroquinolone antibiotics could increase the occurrence of rare but serious events of aortic dissections or ruptures of an aortic aneurysm, which can lead to dangerous bleeding or even death. The FDA is requiring inclusion of these new risks in the prescribing information and patient Medication Guide for all fluoroquinolones. 5. Drug Safety Communication: Risks with Sudden Discontinuation of Opioids educational alert published April 2019 - This alert was based on an FDA warning of reports of serious harm in patients who are physically dependent on opioid pain medicines when these medicines are suddenly discontinued or the dose is rapidly decreased. Examples of serious harm include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. The

	FDA is requiring expanded guidance within the prescribing information of opioids that are intended for use in the outpatient setting on how to safely decrease the dose in patients who are physically dependent on opioids. **6. Drug Safety Communication: Sleep Behavior Risks with Select Sleep Aids** **a. Educational alert published April 2019 - This alert was based on an FDA announcement regarding safety label changes for eszopiclone, zaleplon, and zolpidem because of the risk of complex sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. While rare, these complex sleep behaviors have resulted in serious injuries and death. Safety label changes include a Boxed Warning added to the prescribing information and patient Medication Guides and a Contraindication to avoid use of these drugs in patients who have previously experienced a complex sleep behavior with the use of eszopiclone, zaleplon, and zolpidem.** **b. Provider letter sent August 2019 - The objective was to determine whether there was inappropriate use of zolpidem products, based on FDA warnings that female patients have lower clearance rates than males. Educational outreach letters were mailed on August 20, 2019, to the top 100 prescribers of zolpidem in the Medi-Cal fee-for-service population. Each letter included the Medi-Cal DUR zolpidem alert, a provider response survey, and provider-specific data including the percentage of female Medi-Cal beneficiaries with an initial dose of zolpidem exceeding the recommended initial dosage limits, the percentage of female Medi-Cal beneficiaries with an initial dose of IR zolpidem > 5 mg, and the percentage of female Medi-Cal beneficiaries with an initial dose of ER zolpidem > 6.25 mg.** **7. Tramadol provider letter sent July 2019 - The objective was to inform health care providers and patients of the serious risks attributed to prescribing tramadol to patients younger than 18 years of age. The**

	study population included 40 Medi-Cal fee-for-service beneficiaries younger than 18 years of age (65% were 17 years of age) who had at least one paid claim for tramadol between January 1, 2019 and June 30, 2019. A total of 44 prescribers were identified for educational outreach letters, which were mailed on July 29, 2019. Each letter included patient profiles, the Medi-Cal DUR tramadol alert, and a provider response survey. 8. Codeine provider letter sent August 2019 - The objective was to inform health care providers and patients of the serious risks attributed to prescribing codeine to patients younger than 18 years of age. The study population included 450 Medi-Cal fee-for-service beneficiaries younger than 18 years of age who had at least one paid claim for codeine-containing medication between January 1, 2019 and June 30, 2019. A total of 313 prescribers were identified for educational outreach letters, which were mailed on August 1, 2019. Each letter included patient profiles, both of the Medi-Cal DUR codeine alerts, and a provider response survey. 9. Clinical Review Update: Concomitant Anticholinergic and Antipsychotic Use educational bulletin published August 2019 - This bulletin focused on understanding the role of anticholinergic medications in the prevention and treatment of antipsychotic-induced extrapyramidal symptoms (EPS). The bulletin also describes factors that should be considered when deciding to initiate and/or continue the concomitant use of anticholinergic with antipsychotic medication therapy. 10. 2019 Immunization Updates: Flu, HepA, HPV, Measles, CA School Requirements educational bulletin published September 2019 - This 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 2019 in the United States were also provided. The summary for 2019

	included updates for influenza vaccine, Hepatitis A (HepA) vaccine, human papillomavirus (HPV) vaccine, and measles, as well as a review of changes in vaccination requirements for California schools.

Section IV - DUR BOARD ACTIVITY

Question	Response
1. **Summary 3 – DUR Board Activities Report.** Summary 3 DUR Board Activities Report should be a brief descriptive report on DUR Board activities during the fiscal year reported.	**The DUR Board met four times during FFY 2019.** **Prospective DUR Criteria Presented** **1. Therapeutic Duplication (TD) Alert - An issue was discovered within the Medi-Cal prospective DUR system in which turning off the ingredient duplication (ID) alert for a drug may lead instead to a therapeutic duplication (TD) alert, unless the TD alert is also turned off for a specific drug. This is due to the Duplicate Therapy Module combining ID and TD alerts into one single alert. The issue was discovered when investigating why there were so many TD alerts being generated for quetiapine. The Board had previously recommended turning off the ID alert for quetiapine, which then caused the ID alerts that had been generated by two formulations of quetiapine to instead trigger TD alerts. The same problem was observed with lithium, which had the ID alert turned off for all non-300 mg formulations. The Board recommended to turn off the TD alert for lithium for non-300 mg formulations and to turn back on the ID alert for all formulations of quetiapine, in order to distinguish between true therapeutic duplication with other antipsychotic medications.** **2. Additive Toxicity (AT) Alert: Gabapentinoids - A proposal to add gabapentinoids to the list of drugs for the AT alert based on side effect profile, literature review, and analysis of pharmacy claims data was presented. States are limiting claims to FDA-approved diagnoses or have taken legislative action to classify gabapentin as a scheduled drug, in order to allow gabapentin claims to be reported as part of the prescription drug monitoring program.**

Question	Response
	Effective April 15, 2019, both pregabalin and gabapentin were added to the list of drugs for the AT alert based on side effect profile, literature review, and analysis of pharmacy claims data. An initial review demonstrated a 12% increase in AT alerts since that time, and alert burden will continue to be monitored over time. 3. Review of new Generic Code Number (GCN) sequence numbers: The DUR Board recommended turning on additional alerts for 55 new GCNs that matched drugs appearing on the Medi-Cal target drug list for prospective DUR. Retrospective DUR Criteria Presented 1. Review of Retrospective DUR Criteria: New Additions to the Medi-Cal List of Contract Drugs in FFY 2017 - During FFY 2017 there were a total of 16 new prescription medications added to the Medi-Cal List of Contract Drugs. Utilization data (total number of paid claims and utilizing beneficiaries with at least one paid claim) were reviewed for each of these drugs. Thirteen drugs had low utilization (< 20 utilizing beneficiaries during all of the months reviewed) and were not reported in detail. The Board did not suggest additional evaluation for any of these drugs. 2. Hepatitis C Virus (HCV) Drugs: HCV medication utilization is reviewed on an annual basis, primarily to evaluate potential HCV reinfection and retreatment in the Medi-Cal FFS population. Data showed a 32% decrease in total utilizing beneficiaries with a paid claim for an HCV treatment medication since the previous evaluation. However, after the July 2018 policy change a slight increase was noted in new starts (29.5 in July and August 2018, in comparison to 22.4 new starts in the preceding 10 months). A review of drug utilization over time showed an increase in beneficiaries with paid claims for glecaprevir/pibrentasvir, which was added to the Medi-Cal Fee-for-Service List of Contract Drugs on January 1, 2018. Of note, there were no claims for ombitasvir/paritaprevir/ritonavir/dasabuvir

Question	Response
	or simeprevir during FFY 2018. A review of medical claims data found that all beneficiaries with a paid claim for an HCV treatment medication had at least one HCV-RNA level, HCV genotype test, and comprehensive metabolic panel, which follows AASLD-IDSA recommended guidelines. The Board recommended continuing with annual review. 3. Gabapentinoids - A retrospective DUR review found that a total of 393,514 Medi-Cal enrollees had a paid claim for a gabapentinoid during calendar year 2018, including a total of 38,532 FFS enrollees (4,102 of these were continuously-eligible in the FFS program for all of calendar year 2018). Utilization trends showed increasing use of gabapentinoids over time and only 12% of continuously eligible FFS beneficiaries had an FDA-approved indication for a gabapentinoid within the last five years. The Board agreed that gabapentinoids, specifically gabapentin, should be the topic of an educational bulletin. DUR Board Involvement in Provider-specific Interventions: The DUR Board advises and makes recommendations for educational articles, alerts, and provider intervention letters. The Board chair may appoint a Board member with subject matter expertise to perform a focused review, as appropriate. Educational articles and alerts: 1. Alert: New Naloxone Regulations Effective on January 1, 2019 2. Clinical Review Update: Morphine Equivalent Daily Dose 3. Drug Safety Communication: Updated Adverse Effects from Fluoroquinolones 4. Drug Safety Communication: Risks with Sudden Discontinuation of Opioids 5. Drug Safety Communication: Sleep Behavior Risks with Select Sleep Aids 6. Clinical Review Update: Concomitant Anticholinergic and Antipsychotic Use 7. 2019 Immunization Updates: Flu, HepA, HPV, Measles, CA School Requirements

Question	Response
	Provider intervention letters: **1. Additive Toxicity Letter - January 2019** **2. MEDD - April 2019** **3. Tramadol Letter - July 2019** **4. Codeine Letter - August 2019** **5. Zolpidem Letter - August 2019** **Ongoing DUR Board projects:** **The DUR Board goals for FFY 2019 were as follows:** **1. Advise DHCS regarding the revision of DUR reports to include drugs commonly used in both Medi-Cal Fee-for-Service (FFS) and Managed Care Organizations (MCOs)** **2. Promote dialogue, collaboration among MCOs** **o Present best practices and projects** **o Share innovative ideas and lessons learned** **o Update list of priority areas (topic clusters)** **o Disseminate DUR educational bulletins** **o Integrate/align FFS and MCO DUR action items** **3. Align goals with DHCS Quality Strategy** **o Better health, better care, lower cost** **4. Advise DHCS in the implementation of Medicaid Drug Utilization and Review Minimum Standards for the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act** **5. Priority Area Topic Clusters** **o Optimizing Drug Prescribing and Dispensing, including specialty drugs** **o Optimizing Pain Management and Opioids** **o Optimizing Chronic Disease Management, including prevention**
2. Does your state have an approved Medication Therapy Management Program?	**No**
a. Have you performed an analysis of the program's effectiveness?	**N/A**
"Yes," please provide a brief summary of your findings.	N/A

Question	Response
b. Is your DUR Board involved with this program?	**N/A**
If the answer to question 2 is "No," are you planning to develop and implement a program?	Yes

Section V - PHYSICIAN ADMINISTERED DRUGS

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

Question	Response
1. ProDUR?	**No**
If "No," do you have a plan to include this information in your DUR criteria in the future?	No
2. RetroDUR?	**Yes**
If "No," do you have a plan to include this information in your DUR criteria in the future?	N/A

Section VI - GENERIC POLICY AND UTILIZATION DATA

Question	Response
1. Summary 4 – Generic Drug Substitution Policies Summary 4 Generic Drug Substitution Policies summarizes factors that could affect your generic utilization percentage. Please explain and provide details.	**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.** **2) Carve-out Pharmacy Benefits** **The Medi-Cal fee-for-service program pays**

Question	Response
	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. 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. 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: 1. Maximum Allowable Ingredient Cost (MAIC) plus current professional fee 2. Federal Upper Limit (FUL) plus current professional fees 3. Estimated Acquisition Cost (EAC) plus current professional fees 4. 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

Question	Response
	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.
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
If "Yes," check all that apply.	Other

Question	Response
Other, please explain.	If a brand name drug does not appear on the Medi-Cal List of Contract Drugs, an approved Treatment Authorization Request demonstrating medical necessity may be required before dispensing.

Table 2 - Generic Drug Utilization Data

	Single Source (S) Drugs	Non-Innovator (N) Drugs	Innovator Multi-Source (I) Drugs
Total Number of Claims	1,672,226	7,226,221	678,691
Total Reimbursement Amount Less Co-Pay	$2,849,635,819	$240,267,858	$423,507,461

Question	Response
3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in Table 2 – Generic Drug Utilization Data.	
Number of Generic Claims	7,226,221
Total Number of Claims	9,577,138
Generic Utilization Percentage	75.45%
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 Drug Utilization Data.	
Generic Dollars	$240,267,858
Total Dollars	$3,513,411,138
Generic Expenditure Percentage	6.84%

Section VII - PROGRAM EVALUATION / COST SAVINGS / COST AVOIDANCE

Question	Response
1. **Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance?** If "Yes," identify, by name and type, the institution that conducted the program evaluation.	**Yes**
Institution Type	Academic Institution
Institution Name	University of California, San Francisco (UCSF)
2. **Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below**	

	Data
ProDUR Total Estimated Avoided Costs	$217,616,344.00
RetroDUR Total Estimated Avoided Costs	$0.00
Other Cost Avoidance	$0.00
Grand Total Estimated Avoided Costs	$217,616,344.00

Question	Response
3. **The Estimated Percent Impact was generated by dividing the Grand Total Estimated Avoided Costs from Question 2 above by the Total Dollar Amount provided in Section VI, Question 4, then multiplying this value by 100.** Estimated Percent Impact	**6.19%**
4. **Summary 5 – Cost Savings/Cost Avoidance Methodology** Summary 5 Cost Savings/Cost Avoidance Methodology includes program evaluations/cost savings estimates prepared by state or contractor.	**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:** **1. Discontinuing unnecessary prescriptions** **2. Reducing quantities of medications prescribed** **3. Switching to safer drug therapies** **4. Adding a drug therapy recommended in evidence-based guidelines** **5. 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 FFY 2019 were calculated by taking each individual prospective DUR alert and multiplying the total claims cancelled or not overridden by the average reimbursement dollars paid to pharmacies per claim and a 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) in order to get the total estimated costs avoided through prospective DUR.** **Of note, multiple alerts can be generated per claim, so there may be duplicate alerts cancelled or overridden and the average reimbursement dollars paid to pharmacies per claim was calculated for each alert by looking at the total number of paid claims (including overrides) and total reimbursement dollars paid to pharmacies per claim (does not include adjustment for any rebates) for all drugs that generated that particular alert in FFY 2019.**

Section VIII - FRAUD, WASTE, AND ABUSE DETECTION

A. LOCK-IN or PATIENT REVIEW AND RESTRICTION PROGRAMS

Question	Response
1. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by beneficiaries?	**Yes**
If "Yes," what actions does this process initiate? Check all that apply:	Other
"Other," Please explain	California legislation details available utilization restrictions when the Department has determined that a beneficiary is misusing or abusing Medi-Cal benefits, including being subjected to one or more of the following

Question	Response
	forms of utilization restriction: (1) Prior authorization for all Medi-Cal services. (2) Prior authorization for specific Medi-Cal services. (3) Restriction to utilization of a specific, beneficiary- or Department-selected pharmacy. (4) Restriction to a specific, beneficiary- or Department-selected primary provider of medical services. Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working potential fraud or abuse of controlled drugs by beneficiaries. MRB, SIU, and IB has an intake process for complaints which entails an initial case review and if warranted, assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and trends.
2. **Do you have a Lock-In program for beneficiaries with potential misuse or abuse of controlled substances?** If the answer to question 2 is "Yes," please continue	**No**
a. **What criteria does your state use to identify candidates for Lock-In? Check all that apply:**	**N/A**
"Other," please explain	N/A
b. **Do you have the capability to restrict the beneficiary to:**	
i. Prescriber only	**N/A**
ii. Pharmacy only	**N/A**
iii. Prescriber and Pharmacy	**N/A**
c. **What is the usual Lock-In time period?**	**N/A**
"Other," please explain	N/A
d. **On average, what percentage of the FFS population is in Lock-In status annually?**	**N/A%**
e. **Please provide an estimate of the savings attributed to the Lock-In program for the fiscal year under review as part of Attachment 5.**	**$N/A**

Question	Response
3. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by prescribers?	**Yes**
If "Yes," what actions does this process initiate? Check all that apply:	Deny claims written by this prescriber, Refer to Program Integrity Unit, Other
"Other," please explain	Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working cases involving possible fraud or abuse of controlled drugs by prescribers. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and - if warranted - assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and prescribing trends. Current utilization controls include suspended provider lists, provider sanctions for a specified time period, provider sanctions from prescribing select medications, contracted drug list compliance, code 1 restrictions, treatment authorization requests, maximum dispensing quantity restrictions, and maximum dispensing restrictions during a specified time period.
"No," please explain	N/A
4. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by pharmacy providers?	**Yes**
If "Yes," what actions does this process initiate? Check all that apply:	Refer to Program Integrity Unit, Other
"Other," please explain	Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working cases involving potential fraud or abuse of controlled drugs by pharmacy providers. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and - if warranted - assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and pharmacy dispensing trends.

Question	Response
	Current utilization controls include suspended pharmacy provider lists, restrictions placed upon individual pharmacist licenses by the State Board of Pharmacy, contracted drug list compliance, code 1 restrictions documentation, treatment authorization requests, maximum dispensing quantity restrictions, and maximum dispensing restrictions during a specified time period.
"No," please explain	N/A
5. **Do you have a documented process in place that identifies and/or prevents potential fraud or abuse of non-controlled drugs by beneficiaries?**	**Yes**
"Yes," please explain your program for fraud, waste, or abuse of non-controlled substances.	Audit & Investigations, Medical Review Branch (MRB), Special Investigative Unit (SIU) or Investigations Branch (IB) is responsible for working potential fraud or abuse of non-controlled drugs by beneficiaries. MRB, SIU, and IB has an intake process for complaints that entails an initial case review and - if warranted - assignment of a case to an investigator/auditor. Subsequent actions are dependent upon the outcome of the investigation, which looks at claims data and trends.
"No," please explain	**N/A**

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Question	Response
1. **Does your state have a Prescription Drug Monitoring Program (PDMP)?** If the answer to question 1 is "Yes," please continue with a, b, and c.	**Yes**
a. **Does your agency have the ability to query the state's PDMP database?** If the answer to sub-question 1 a is "Yes," please continue.	**Yes, we have access to the database**
i. 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,

Question	Response
	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. Audit & Investigations, Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations. IB also examines PDMP information on prescribers, dispensers, and beneficiaries during the course of their usual work.
ii. Do you also have access to Border States' PDMP information?	No
iii. Do you also have PDMP data (i.e. outside of MMIS, such as a controlled substance that was paid for by using cash) integrated into your POS edits?	No
b. Do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before prescribing controlled substances?	**No**
c. 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**
"Yes," please explain the barriers (i.e. lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script).	The following barriers exist that hinder the agency from fully accessing the PDMP in the way it was intended: 1. Inability to access border states' PDMP information 2. Lag time for prescription data being submitted 3. Ambiguous regulations governing access to PDMP data
2. 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**

Question	Response
"Yes," please explain.	Effective for dates of service on or after October 2, 2018, it is now mandatory to consult the CURES 2.0 database prior to prescribing, ordering, administering, or furnishing a Schedule II - IV controlled substance.

C. PAIN MANAGEMENT CONTROLS

Question	Response
1. **Does your program obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?** If the answer to question 1 is "Yes," please continue.	**No**
a. **Do you apply this DEA file to your ProDUR POS edits to prevent unauthorized prescribing?**	**N/A**
If "Yes," please explain how information is applied.	N/A
If "No," do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?	N/A
If "No," please explain	N/A
b. **Do you apply this DEA file to your RetroDUR reviews?**	**N/A**
If "Yes," please explain how it is applied.	N/A
2. **Do you have a measure (i.e. prior authorization, quantity limits) in place to either monitor or manage the prescribing of methadone for pain management?**	**Yes**
If "No," please explain why you do not have a measure in place to either manage or monitor the prescribing of methadone for pain management.	N/A

D. OPIOIDS

Question	Response
1. **Do you currently have a POS edit in place to limit the quantity dispensed of an initial opioid prescription?**	**Yes, for some opioids**

Question	Response
If the answer to question 1 is "Yes, for all opioids" or "Yes, for some opioids," please continue.	
Please explain answer above.	Opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.
a. **Is there more than one quantity limit for the various opioids?**	**Yes**
"Yes," please explain	Opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.
b. **What is the maximum number of days' supply allowed for an initial opioid prescription?**	**100**
c. **Does this days' supply limit apply to opioid prescriptions?**	**Yes, for some opioids**
"No," please explain	N/A
2. **For subsequent prescriptions, do you have POS edits in place to limit the quantity dispensed of short-acting opioids?**	**Yes**
If "Yes," what is your maximum days' supply per prescription limitation?	Other
"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.
If "No," please explain	N/A
3. **Do you currently have POS edits in place to limit the quantity dispensed of long-acting opioids?**	**Yes**
If "Yes," what is your maximum days' supply per prescription limitation?	90 day supply
"Other," please explain	N/A
If "No," please explain	N/A
4. **Do you have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids?**	**Yes**
If "Yes," check all that apply:	Deny claim and require PA, Intervention letters, Morphine Milligram Equivalent (MME) daily dose program, Require PDMP checks, Workgroups to address opioids
Please provide details on these opioid prescribing controls in place.	Deny claim and require PA - Restrictions that may deny claim and require PA include, but are not limited to, age restrictions and duration of therapy restrictions.

Question	Response
	Intervention letters - In FFY 2019, intervention letters were sent to prescribers for the following topics: 1. Patients at high-risk for adverse events associated with the use of certain opioid medications in combination with benzodiazepines and other CNS depressants 2. Patients with at least one paid claim > 120 mg MME/day 3. Patients under 18 years of age with a paid claim for tramadol and/or codeine Morphine Milligram Equivalent (MME) daily dose program - For the treatment of chronic pain, dose is to not exceed 500 MME/daily without an approved Treatment Authorization Request. This safety edit assists in identifying members at potentially high-clinical risk who may benefit from close monitoring and care coordination. Require PDMP checks - Assembly Bill 2760 (Wood, Chapter 324) was signed into law in 2018 and became effective on January 1, 2019. California prescribers are now required to offer a prescription to a patient for either naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid-induced respiratory depression, as a rescue medication when one or more of the following conditions are present: 1. The prescription dosage for the patient is greater than or equal to 90 mg MME/day 2. An opioid medication is prescribed concurrently with a prescription for a benzodiazepine. 3. The patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or a risk for returning to a high dose of opioid medication to which the patient is no longer tolerant. The bill also requires a prescriber, consistent with the existing standard of care, to provide education on overdose prevention and the use

Question	Response
	of naloxone or other similar drug approved by the FDA to a patient and his or her designee or, if the patient is a minor, to the patient's parent or guardian. Workgroups to address opioids - California has a Prescription Drug Overdose Prevention Initiative. The goals of the initiative include increasing the number of active buprenorphine prescribers, increasing the number of naloxone claims, decreasing all-cause overdose mortality, reducing the concomitant use of benzodiazepines and opioids, and reducing opioid claims > 90 mg MEDD.
If "No," 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 opioids.	N/A
5. Do you have POS edits to monitor duplicate therapy of opioid prescriptions?	**Yes**
Please explain	POS edits are in place to monitor duplicate therapy of opioid prescriptions that do not have an approved Treatment Authorization Request.
6. Do you have POS edits to monitor early refills of opioid prescriptions dispensed?	**Yes**
Please explain	POS edits are in place to monitor early refills of opioid prescriptions that do not have an approved Treatment Authorization Request.
7. Do you have comprehensive claims review automated retrospective process to monitor opioid prescriptions exceeding these state limitations?	**No**
Please explain	While there is regular, comprehensive claims review to monitor opioid prescriptions exceeding these state limitations, the review process is not automated.
8. Do you currently have POS edits in place or a retrospective claims review to monitor opioids and benzodiazepines being used concurrently?	**Yes, both POS edits and retrospective reviews**
If "Yes," Please explain in detail scope and nature of reviews and edits.	Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle

Question	Response
	relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties. Two mailings on this topic were initiated in FFY2019 after retrospective reviews showed beneficiaries with concurrent use of opioids, benzodiazepines, and additional medications with CNS depressant properties.
If "No," Please explain	N/A
9. Do you currently have POS edits in place or a retrospective claims review to monitor opioids and sedatives being used concurrently?	**Yes, POS edits only**
If "Yes," Please explain in detail scope and nature of reviews and edits.	**Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties.**
If "No," Please explain	**N/A**
10. Do you currently have POS edits in place or a retrospective claims review to monitor opioids and antipsychotics being used concurrently?	**Yes, POS edits only**
If "Yes," Please explain in detail scope and nature of reviews and edits.	Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties.
If "No," Please explain	N/A

Question	Response
11. Do you have POS safety edits or perform RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?	**Yes, retrospective reviews only**
If "Yes," retrospective reviews are performed, please indicate how often.	Ad hoc
"Other," please specify.	N/A
Please explain nature and scope of edits, reviews and/or provider education reviews performed.	Retrospective reviews of beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis are performed annually and on an ad-hoc basis. For FFY 2019, provider education efforts included sending educational outreach letters to all prescribers of opioids to beneficiaries with at least one paid claim greater than or equal to 120 morphine mg equivalents per day. Patient profiles included outpatient office visits, emergency department visits, and inpatient hospitalizations where a diagnosis of opioid use disorder and/or opioid poisoning was indicated.
If "No," do you plan on implementing a RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?	N/A
If "No," Please explain.	N/A
12. Does your state Medicaid agency develop and provide prescribers with pain management or opioid prescribing guidelines?	**Yes**
If "Yes," please check all that apply	Your state Medicaid agency refers prescribers to the CDC's Guideline for Prescribing Opioids for Chronic Pain., Other guidelines.
Please identify the "other" guidelines.	The Medical Board of California Guidelines for Prescribing Controlled Substances for Pain
Please explain why no guidelines are offered.	N/A
13. Do you have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e. presence of an abuse deterrent opioid with preferred status on your preferred drug list)?	**Yes**
"Yes," please explain	Effective August 1, 2017, multiple strengths of morphine sulfate/naltrexone were added to the Medi-Cal List of Contract Drugs.

E. MORPHINE MILLIGRAM EQUIVALENT (MME) DAILY DOSE

Question	Response
1. Have you set recommended maximum MME daily dose measures?	**Yes**
If "Yes," please continue	
a. What is your maximum morphine equivalent daily dose limit in milligrams?	**Other mg per day**
i. If "Other", please specify	**500 mg per day**
b. Please explain nature and scope of dose limit.	**For the treatment of chronic pain, dose is to not exceed 500 MME/daily without an approved treatment authorization request. This safety edit assists in identifying members at potentially high-clinical risk who may benefit from close monitoring and care coordination.**
If "No," please explain the measure or program you utilize.	**N/A**
2. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere?	**Yes**
a. If "Yes," Please name the developer of the calculator:	**CDC**
If "Other," please specify	N/A
b. If "Yes," how is the information disseminated? Check all that apply:	**Website, Provider notice, Other**
If "Other," please explain	In February 2019, the Medi-Cal DUR program published an educational bulletin - Clinical Review Update: Morphine Equivalent Daily Dose - 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 edit in your POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded?	**No**
If "Yes," do you require prior authorization if the MME limit is exceeded?	N/A

Question	Response
4. Do you have automated retrospective claim reviews to monitor total daily dose (MME) of opioid prescriptions dispensed?	**No**
Please explain	We have completed several retrospective claim reviews to monitor total daily dose (MME) of opioid prescriptions dispensed, but they are not automated.

F. BUPRENORPHINE, NALOXONE, BUPRENORPHINE/NALOXONE COMBINATIONS and METHADONE for OPIOID USE DISORDER (OUD)

Question	Response
1. Does your agency set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?	**Yes**
If "Yes," please specify the total mg/day:	Other
If "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?	**No limit**
If "Other," please explain	N/A
3. Do you require that the maximum mg per day allowable be reduced after a set period of time? If "Yes," please continue	**No**
a. What is your reduced (maintenance) dosage?	**N/A**
If "Other," please explain	N/A
b. What are your limitations on the allowable length of the reduced dosage treatment?	**N/A**
If "Other," please explain	N/A
4. Do you have at least one buprenorphine/naloxone combination product available without prior authorization?	**Yes**
5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug or any form of MAT?	**No**
"Other," please explain	N/A
If "Yes," can the POS pharmacist override the edit?	N/A
6. Do you have at least one naloxone opioid overdose product available without prior authorization?	**Yes**

Question	Response
7. Do you retrospectively monitor and manage appropriate use of naloxone to persons at risk of overdose?	**Yes**
Please explain	There have been multiple retrospective reviews to identify persons at risk of overdose. Provider outreach to prescribers is ongoing and information has been provided to these prescribers regarding appropriate use of naloxone. Assembly Bill 2760 (Wood, Chapter 324) was signed into law in 2018 and became effective on January 1, 2019. California prescribers are now required to offer a prescription to a patient for either naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid-induced respiratory depression, as a rescue medication when one or more of the following conditions are present: 1. The prescription dosage for the patient is greater than or equal to 90 mg MME/day. 2. An opioid medication is prescribed concurrently with a prescription for a benzodiazepine. 3. The patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or a risk for returning to a high dose of opioid medication to which the patient is no longer tolerant. The bill also requires a prescriber, consistent with the existing standard of care, to provide education on overdose prevention and the use of naloxone or other similar drug approved by the FDA to a patient and his or her designee or, if the patient is a minor, to the patient's parent or guardian.
8. Does your State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid agency allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?	**Yes, State Board of Professional Regulations/Board of Pharmacy/ Board of Medicine and/or State Medicaid agency under protocol**

Question	Response
9. Does your state agency cover methadone for a substance use disorder (i.e. Methadone Treatment Center)?	**Yes**

G. ANTIPSYCHOTICS / STIMULANTS

ANTIPSYCHOTICS

Question	Response
1. Do you currently have restrictions in place to limit the quantity of antipsychotics?	**No**
Please explain	An approved Treatment Authorization Request is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 - 17 years of age. An approved Treatment Authorization Request is also required for beneficiaries residing in skilled nursing facilities (SNFs).
2. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?	**Yes**
a. If "Yes," do you either manage or monitor:	**All children**
"Other," please explain	N/A
b. If "Yes," do you have edits in place to monitor (check all that apply):	**Child's age, Dosage, Indication, Polypharmacy**
"Other" Please explain	N/A
c. Please briefly explain the specifics of your antipsychotic monitoring 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 - 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**

Question	Response
	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.
d. If "No," do you plan on implementing a program in the future?	**N/A**
If "Yes," when do you plan on implementing a program?	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A

STIMULANTS

Question	Response
3. Do you currently have restrictions in place to limit the quantity of stimulants?	**No**
4. **Do you have a documented program in place to either manage or monitor the appropriate use of stimulant drugs in children?**	**Yes**
a. If "Yes," Do you either manage or monitor:	**All children**
"Other," please explain	N/A
b. If "Yes," Do you have edits in place to monitor (check all that apply):	**Child's age, Indication**
"Other," please explain	N/A
c. Please briefly explain the specifics of your documented stimulant monitoring program(s).	**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.**
d. If "No," do you plan on implementing a program in the future?	**N/A**
If "Yes," when do you plan on implementing a program?	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children	N/A

Section IX - INNOVATIVE PRACTICES

Question	Response
1. **Summary 6 – Innovative Practices** Summary 6 - Innovative Practices should discuss development of innovative practices during the past year (i.e. Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MME, and Value Based Purchasing).	**The Medi-Cal DUR Program plays an integral role in the Department of Health Care Services' Strategy for Quality Improvement in Healthcare initiative. DHCS continues to collaborate statewide to prevent prescription drug overdose, including with the state's Prescription Drug Overdose Prevention Initiative. The overarching strategy for this initiative includes safe prescribing, access to treatment, naloxone distribution, a public education campaign, and data informed and driven interventions. The goals of the initiative include increasing the number of active buprenorphine prescribers, increasing the number of naloxone claims, decreasing all-cause overdose mortality, reducing the concomitant use of benzodiazepines and opioids, and reducing opioid claims > 90 mg MEDD.** **The DUR program also helped disseminate important materials and resources developed elsewhere in the state, including the California Health Care Foundation's Opioid Safety Toolkit, information about the Naloxone Distribution Project (NDP), a project funded by SAMHSA and administered by DHCS to combat opioid overdose-related deaths throughout California, and resources available from the California State Board of Pharmacy, including a no-cost webinar that fulfills the training requirement for pharmacists to furnish naloxone to patients without a prescription and a revised training guide entitled Opioid Safety: Focus on Furnishing Naloxone - A Guide for California Community Pharmacists. In addition, California Assembly Bill 2760 (Wood, Chapter 324) was signed into law in 2018 and became effective on January 1, 2019. AB 2760 requires California prescribers to offer a prescription to a patient for either naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid-induced respiratory depression, as a rescue medication under certain conditions.**

Question	Response
	In order to continue addressing polypharmacy of CNS depressants, the DUR Board had previously recommended that the additive toxicity (AT) alert be updated to reflect only additive toxicity effects from multiple CNS depressants, including opioids, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with CNS depressant properties. In FFY 2019, gabapentinoids were added to the list of drugs that could generate an AT alert and, as a result, gabapentin was the top drug to generate AT alerts in FFY 2019. **Both independently and in collaboration, 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.**

Section X - E-PRESCRIBING

Question	Response
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?	**No**
If "Yes," do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?	N/A
If "Yes," please explain the evaluation methodology. **Summary 7 –E-Prescribing Activity** should explain the evaluation methodology utilized in evaluate the effectiveness of providing drug information and medication history prior to prescribing.	N/A
If "No," are you planning to develop this capability?	No
If "No," please explain	Current system does not allow for this capability.

Question	Response
2. Does your system use the NCPDP Origin Code that indicates the prescription source?	**No**

Section XI - MANAGED CARE ORGANIZATIONS (MCOs)

Question	Response
1. How many MCOs are enrolled in your state Medicaid program?	**26**
2. Is your pharmacy program included in the capitation rate (carved in)?	**Partial**
If "Partial," please specify the drug categories that are carved out.	Carved out drugs have some variation from plan to plan, but in general include: 1. Selected HIV/AIDS/Hepatitis B treatment drugs; 2. Selected alcohol and heroin detoxification and dependency treatment drugs; 3. Selected coagulation factors; and 4. 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**
a. If "Yes," please check all requirements that apply	**Formulary Reviews**
b. 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.** **Starting in FFY 2018, the DUR Board expanded to become the Global Medi-Cal DUR Board, with MCO representatives now included as Board members. MCOs utilize the Global Medi-Cal DUR Board and educational components of the Medi-Cal DUR program.**

Question	Response
	However, MCOs maintain their current proprietary claims processing procedures and protocols and MCPs individually administer the systematic components related to the prospective and retrospective DUR processes. As is the case with the Fee-For-Service (FFS) program, MCOs are not required to implement all DUR Board recommended actions, nor are they required to mirror the Medi-Cal DUR activities.
If "No," do you plan to set standards in the future?	N/A
If "No," please explain	N/A
4. Did all of your managed care plans submit their DUR reports?	**Yes**
If "No," please explain.	N/A

Section XII – EXECUTIVE REPORT

Question	Response
Summary 8-Executive Report should provide a brief overview of your program. It should describe 2019 highlights of the program, FFS initiatives, improvements, program oversight of managed care partners when applicable, and statewide (FFS and MCO) initiatives.	**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 and pharmacies.** **During federal fiscal year (FFY) 2019, California's Global Medi-Cal DUR Board (the Board) included ten pharmacists and six physicians, meeting OBRA 1990 requirements. The Board held four meetings in FFY 2019, 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 Board is responsible for advising and**

Question	Response
	making recommendations to DHCS for the Medi-Cal population. Over the course of FFY 2019 the Board reviewed prospective DUR criteria for 55 drugs and comprehensively reviewed the status of ingredient duplication (ID) and therapeutic duplication (TD) alerts for lithium and quetiapine. In addition, retrospective DUR criteria for Hepatitis C Virus (HCV) medications and gabapentinoids, as well as all medications that became available on the Medi-Cal Contract Drugs List in FFY 2018 were presented to the Board. A total of 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. A total of five educational mailings were sent to selected prescribers to improve the quality of care for Medi-Cal beneficiaries. Finally, in FFY 2018, the Board continued to collaborate with key state agencies and national experts, and actively worked to incorporate a variety of Medi-Cal MCP best practices across multiple plans into the Board meeting agenda. This Annual Report was prepared through a collaborative effort between the California Department of Health Care Services, the Global Medi-Cal Drug Use Review Board, DXC Technology, Inc., and the University of California, San Francisco.