STATE OF CALIFORNIA — DEPARTMENT OF FINANCE

ECONOMIC AND FISCAL IMPACT STATEMENT (REGULATIONS AND ORDERS)

STD. 399 (REV. 12/2013)

ECONOMIC IMPACT STATEMENT

DEPARTMENT NAME	CONTACT PERSON	EMAIL ADDRESS	TELEPHONE NUMBER
Department of Industrial Relations	Jacqueline Schauer	jschauer@dir.ca.gov	510.286.0563
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400: Medical Treatment Utilization Schedule Drug Formulary			NOTICE FILE NUMBER: Z

A. ESTIMATED PRIVATE SECTOR COST IMPACTS *Include calculations and assumptions in the rulemaking record.*

1. Check the appropriate box(es) below to indicate whether this regulation:

- [X] a. Impacts business and/or employees
- [X] b. Impacts small businesses
- [X] c. Impacts jobs or occupations
- [X] d. Impacts California competitiveness
- [ ] e. Imposes reporting requirements
- [ ] f. Imposes prescriptive instead of performance
- [X] g. Impacts individuals
- [ ] h. None of the above (Explain below):

If any box in Items 1 a through g is checked, complete this Economic Impact Statement.
If box in Item 1.h. is checked, complete the Fiscal Impact Statement as appropriate.

2. The ______ (Agency/Department) estimates that the economic impact of this regulation (which includes the fiscal impact) is:

- [ ] Below $10 million
- [ ] Between $10 and $25 million
- [X] Between $25 and $50 million
- [ ] Over $50 million *[If the economic impact is over $50 million, agencies are required to submit a Standardized Regulatory Impact Assessment as specified in Government Code Section 11346.3(c)]*

3. Enter the total number of businesses impacted: 1,424,141

Describe the types of businesses (Include nonprofits): All California business (see attachment).

Enter the number or percentage of total businesses impacted that are small businesses: 98.3%

4. Enter the number of businesses that will be created: 0 eliminated: 0

Explain: We assume that costs and benefits will be borne by existing businesses and will not create or eliminate businesses.

5. Indicate the geographic extent of impacts: [X] Statewide [ ] Local or regional (List areas):

6. Enter the number of jobs created: 140 and eliminated: 41

Describe the types of jobs or occupations impacted: Costs and benefits are multiplier impacts that are spread across all industries. The estimated impacts are relatively small and apply to a large number of industries.

7. Will the regulation affect the ability of California businesses to compete with other states by making it more costly to produce goods or services here? [ ] YES [X] NO

If YES, explain briefly:

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ECONOMIC IMPACT STATEMENT (CONTINUED)

B. ESTIMATED COSTS *Include calculations and assumptions in the rulemaking record.*

1. What are the total statewide dollar costs that businesses and individuals may incur to comply with this regulation over its lifetime? $ $10,435,000 (12m

   a. Initial costs for a small business: $ See attachment Annual ongoing costs: $ See attachment Years: 2018-2019

   b. Initial costs for a typical business: $ See attachment Annual ongoing costs: $ See attachment Years: 2018-2019

   c. Initial costs for an individual: $ See attachment Annual ongoing costs: $ See attachment Years: 2018-2019

   d. Describe other economic costs that may occur: See attachment.

2. If multiple industries are impacted, enter the share of total costs for each industry: The only estimated cost is for physician practices and other providers that directly dispense prescription drugs to injured workers. See attachment.

3. If the regulation imposes reporting requirements, enter the annual costs a typical business may incur to comply with these requirements. *Include the dollar costs to do programming, record keeping, reporting, and other paperwork, whether or not the paperwork must be submitted.* $0

4. Will this regulation directly impact housing costs? ☐ YES ☒ NO

   If YES, enter the annual dollar cost per housing unit: $

   Number of units:

5. Are there comparable Federal regulations? ☐ YES ☒ NO

   Explain the need for State regulation given the existence or absence of Federal regulations: N/A. Regulations are necessary based on a State statutory mandate.

   Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: $ 0

C. ESTIMATED BENEFITS *Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. Briefly summarize the benefits of the regulation, which may include among others, the health and welfare of California residents, worker safety and the State's environment: Reduced workers compensation premiums for all businesses in California that purchase/provide workers' compensation insurance. See attachment for additional detail.

2. Are the benefits the result of: ☒ specific statutory requirements, or ☐ goals developed by the agency based on broad statutory authority?

   Explain: Labor Code section 5307.27 mandates the creation of an evidence-based drug formulary as part of the MTUS.

3. What are the total statewide benefits from this regulation over its lifetime? $ $35,428,000 (12 mo.)

4. Briefly describe any expansion of businesses currently doing business within the State of California that would result from this regulation: These are multiplier benefits that arise from decreased costs to firms and are spread across the entire economy. They are relatively small benefits that accrue to a large number of businesses. See attachment.

D. ALTERNATIVES TO THE REGULATION *Include calculations and assumptions in the rulemaking record. Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. List alternatives considered and describe them below. If no alternatives were considered, explain why not: See attachment.

ECONOMIC IMPACT STATEMENT (CONTINUED)

2. Summarize the total statewide costs and benefits from this regulation and each alternative considered:

Regulation: Benefit: $ $35,428,000 Cost: $ $10,435,000

Alternative 1: Benefit: $ $35,409,000 Cost: $ $10,466,000

Alternative 2: Benefit: $ NA Cost: $ NA

3. Briefly discuss any quantification issues that are relevant to a comparison of estimated costs and benefits for this regulation or alternatives: See attachment.

4. Rulemaking law requires agencies to consider performance standards as an alternative, if a regulation mandates the use of specific technologies or equipment, or prescribes specific actions or procedures. Were performance standards considered to lower compliance costs? ☐ YES ☒ NO

Explain: N/A. A drug formulary neither contains nor establishes objective criteria from which performance can be measured or assessed.

E. MAJOR REGULATIONS *Include calculations and assumptions in the rulemaking record.*

California Environmental Protection Agency (Cal/EPA) boards, offices and departments are required to submit the following (per Health and Safety Code section 57005). Otherwise, skip to E4.

1. Will the estimated costs of this regulation to California business enterprises **exceed $10 million?** ☐ YES ☐ NO

If YES, complete E2. and E3
If NO, skip to E4

2. Briefly describe each alternative, or combination of alternatives, for which a cost-effectiveness analysis was performed:

Alternative 1: ____________________

Alternative 2: ____________________

(Attach additional pages for other alternatives)

3. For the regulation, and each alternative just described, enter the estimated total cost and overall cost-effectiveness ratio:

Regulation: Total Cost $ __________ Cost-effectiveness ratio: $ __________

Alternative 1: Total Cost $ __________ Cost-effectiveness ratio: $ __________

Alternative 2: Total Cost $ __________ Cost-effectiveness ratio: $ __________

4. Will the regulation subject to OAL review have an estimated economic impact to business enterprises and individuals located in or doing business in California exceeding $50 million in any 12-month period between the date the major regulation is estimated to be filed with the Secretary of State through12 months after the major regulation is estimated to be fully implemented?

☐ YES ☒ NO

If YES, agencies are required to submit a Standardized Regulatory Impact Assessment (SRIA) as specified in Government Code Section 11346.3(c) and to include the SRIA in the Initial Statement of Reasons.

5. Briefly describe the following:

The increase or decrease of investment in the State: N/A

The incentive for innovation in products, materials or processes: N/A

The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among any other benefits identified by the agency: See attached.

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FISCAL IMPACT STATEMENT

A. FISCAL EFFECT ON LOCAL GOVERNMENT *Indicate appropriate boxes 1 through 6 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

☐ 1. Additional expenditures in the current State Fiscal Year which are reimbursable by the State. (Approximate)
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

$ ____________________

☐ a. Funding provided in ____________________

Budget Act of __________ or Chapter __________ , Statutes of __________

☐ b. Funding will be requested in the Governor's Budget Act of ____________________

Fiscal Year: __________

☐ 2. Additional expenditures in the current State Fiscal Year which are NOT reimbursable by the State. (Approximate)
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

$ ____________________

Check reason(s) this regulation is not reimbursable and provide the appropriate information:

☐ a. Implements the Federal mandate contained in ____________________

☐ b. Implements the court mandate set forth by the ____________________ Court.

Case of: ____________________ vs. ____________________

☐ c. Implements a mandate of the people of this State expressed in their approval of Proposition No. __________

Date of Election: ____________________

☐ d. Issued only in response to a specific request from affected local entity(s).

Local entity(s) affected: ____________________

☐ e. Will be fully financed from the fees, revenue, etc. from: ____________________

Authorized by Section: __________ of the __________ Code;

☐ f. Provides for savings to each affected unit of local government which will, at a minimum, offset any additional costs to each;

☐ g. Creates, eliminates, or changes the penalty for a new crime or infraction contained in ____________________

☒ 3. Annual Savings. (approximate)

$ $3,443,000 (see attachment)

☐ 4. No additional costs or savings. This regulation makes only technical, non-substantive or clarifying changes to current law regulations.

☐ 5. No fiscal impact exists. This regulation does not affect any local entity or program.

☐ 6. Other. Explain ____________________

FISCAL IMPACT STATEMENT (CONTINUED)

B. FISCAL EFFECT ON STATE GOVERNMENT *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

☐ 1. Additional expenditures in the current State Fiscal Year. (Approximate)

$ ____________

It is anticipated that State agencies will:

☐ a. Absorb these additional costs within their existing budgets and resources.

☐ b. Increase the currently authorized budget level for the ____________ Fiscal Year

☒ 2. Savings in the current State Fiscal Year. (Approximate)

$ $803,000 (see attachment)

☐ 3. No fiscal impact exists. This regulation does not affect any State agency or program.

☐ 4. Other. Explain ____________

C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

☐ 1. Additional expenditures in the current State Fiscal Year. (Approximate)

$ ____________

☐ 2. Savings in the current State Fiscal Year. (Approximate)

$ ____________

☒ 3. No fiscal impact exists. This regulation does not affect any federally funded State agency or program.

☐ 4. Other. Explain ____________

FISCAL OFFICER SIGNATURE	DATE
Jay Sturgess	3/2/17

The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6601-6616, and understands the impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.

AGENCY SECRETARY	DATE
	3·6·17

Finance approval and signature is required when SAM sections 6601-6616 require completion of Fiscal Impact Statement in the STD. 399.

DEPARTMENT OF FINANCE PROGRAM BUDGET MANAGER	DATE

STD 399. Economic and Fiscal Impact Statement
Supplemental information
Medical Treatment Utilization Schedule - Formulary
Department of Industrial Relations Division of Workers Compensation

Attachment: Additional Detail for Select Response Fields

A. Estimated private sector cost impacts

A3. All California businesses are required to purchase workers' compensation insurance or self-insure against losses related to workplace injuries (see Labor Code Section 3700). The California Employment Development Department (EDD), Labor Market Information Division estimates that there were 1,424,141 businesses in California in the third quarter of 2015.[1] California Government Code section 11346.3 defines small businesses as businesses that are independently owned and operated, not dominant in their field of operation, and have fewer than 100 employees. EDD reports that 98.3% of the businesses in California have fewer than 100 employees.

B. Estimated costs

B1. Estimated costs include reduced net income for physician practices and other health care providers. The reduction in net income is due to lower rates of physician dispensing of drugs. In 2014, physician-dispensed drugs accounted for about half of California workers' compensation prescribing. Under physician prescribing, physician practices and other providers purchase and stock drugs from wholesalers or manufacturers, dispense prescription drugs directly to injured workers, and then bill directly for the dispensed drug. Physicians retain as net income the margin between the payment rate and the acquisition cost. In many cases, the prices for physician-dispensed drugs are higher than similar pharmacy-dispensed drugs. The regulation requires prospective review for physician dispensed drugs except in a small number of exceptions (including a first fill policy designed to ensure access to necessary prescriptions shortly after an injury and while the prospective review is in progress). As a result of this prospective review requirement, we estimate that physicians will dispense fewer prescriptions and that some of these prescriptions will transition to pharmacy-dispensed prescriptions.

The net income for many physician dispensed drugs will decrease over time as a result of California workers' compensation fee schedule changes that are separate from the formulary regulation. In particular, the fee schedule will use updated Federal Upper Limit (FUL) rates that are closely aligned to acquisition cost. In order to estimate the change in physician net income associated with the reduction in physician-dispensed prescription volume alone (and not changes in fee schedule prices), we based our estimate on physician-dispensed prescription fill data from the California Workers' Compensation Information System (WCIS) database for national drug codes (NDCs) without an updated FUL rate. We used average acquisition cost

[1] Available at: http://www.labormarketinfo.edd.ca.gov/LMID/Size_of_Business_Data.html

information from the Centers for Medicaid and Medicare Services[2] adjusted upwards by 10% to account for lower negotiating power for physician practices compared to pharmacies. Average acquisition prices were applied at the drug ingredient-form level, or, if an acquisition price was not available, we assumed the acquisition price was one-half the observed price (which was the average observed empirical relationship between price and acquisition cost where both data points were available).

We calculated the change in physician net income as the product of the difference in volume before and after the formulary regulation and the difference between the observed physician-dispensed price and average acquisition cost. The change in volume was based on assumptions that a small share (20%) of physician-dispensed prescriptions would not be written due to the prospective review requirement and that a larger share (40%) of physician-dispensed volume would transition to pharmacy-dispensed alternatives. We assume that two-thirds of the ultimate reduction in physician net income would occur in the first year after the regulation is implemented and that later years would experience the full impact of the regulation on prescribing behavior.

The estimated total cost in the initial 12-month period after the regulation is implemented is $10,435,000. This estimate includes a $6,760,000 reduction in net income for physician practices and other providers dispensing drugs directly to injured workers and a $3,765,000 reduction in state Gross State Product (GSP) driven by lower physician practice net income.

We also expect reductions in pharmacy-dispensed prescription volume due to prospective review. These reductions may translate to lower revenue for pharmacies and drug manufacturers. We did not estimate these potential changes in revenue due to: (1) small margins on individual prescriptions at dispensing pharmacies (typically a modest dispensing fee); (2) the fact that most pharmaceutical manufacturers are national or multi-national firms; and (3) offsetting increases in revenue for pharmacies and drug manufacturers as prescribers shift from physician-dispensed to pharmacy-dispensed drugs and increase utilization of preferred drugs.

B1a-c Based on our analysis of WCIS data, approximately 3,200 physician practices defined by Tax Identification Number (TIN) had at least one physician-dispensed prescription paid bill in 2014. While there is considerable variation in how practices and individual practitioners report TIN on health care bills, it is the best proxy for identifying specific practices as businesses given the available data. Of these, approximately 75 percent had one physician only, 5 percent had four or more physicians, 2 percent had more than 10 physicians, and 0.5 percent had more than 20 individual physicians (and likely fewer than 100 employees total) defined by National Provider Identification (NPI) number where NPI information was available. By apportioning the total estimated costs for a 12-month period reflecting the full impact of the regulation on prescribing behavior (Q2 2018 through Q1 2019) to individual prescribers with physician-administered drugs

[2] Available at: https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html

and then aggregating these costs to TINs, we estimate that the cost per small practice (defined as practices with three or fewer physicians) currently dispensing drugs to injured workers as $850 (B1a). Because more than 90 percent of physician practices dispensing drugs to injured workers have three or fewer individual practitioners, we define the "typical" practice as these physician practices (B1b). We estimate that the cost per individual practice (overall) with physician-dispensed prescriptions in 2014 as $3,300 (B1c).

B1d. We did not explicitly estimate implementation costs because adapting to new workers' compensation regulations is part of routine business for workers' compensation insurers, payers, adjudicators, and practitioners and other providers. Prescribers already need access to the ACOEM Treatment Guidelines to write prescriptions consistent with the workers' compensation Medical Treatment Utilization Schedule (MTUS) treatment guidelines.

B2. See comments for B1d.

C. Estimated benefits

C1. The formulary will guide prescribers towards a set of preferred drugs and uses that are consistent with California workers' compensation treatment guidelines. Preferred drugs will not be subject to prospective review. Other formulary provisions requiring prospective review for brand-name drugs dispensed when an equivalent generic is available, for compounded drugs, and for physician-dispensed drugs will help shift prescribing volume to preferred drugs where appropriate. Overall, we estimate that the formulary will reduce the total number of prescriptions received by injured workers in four categories: (1) brand-name drugs where equivalent generic drugs are available; (2) non-preferred drugs in therapeutic classes where a preferred drug is available; (3) physician-dispensed drugs where pharmacy-dispensed drugs are available; and (4) bulk ingredients used to make compounded drugs. The reductions in prescribing volume and costs in these categories will be partially – but not completely – offset by increases in generic drug, preferred drug, and pharmacy-dispensed drug fills and spending.

These changes will decrease California workers' compensation spending on prescription drugs by an estimated $22,951,000. Lower spending on prescription drugs will translate into reductions in workers' compensation premiums of approximately the same amount. We estimate the benefits from these changes in the initial 12-month period after the regulation is fully implemented will be $35,428,000, including the reduction in spending on prescription drugs and a $12,477,000 increase in GSP resulting from these savings in workers' compensation costs. We estimate that these annual savings will increase by 50% in the next 12-month period and then subsequently decline as prescriber behavior adapts to the drug listing and formulary provisions. These estimates are based on an assumption that prescribers will not substitute NSAID analgesics in place of opioid analgesics. Total benefits are higher - $39,904,000 in total including $25,850,000 in savings to employers and a $14,053,000 increase in GSP – when NSAIDs and opioid analgesics are combined in a single analgesic class. The larger benefits are due to substitution of lower-cost NSAIDs in place of discontinued opioid prescription fills.

The formulary may have other benefits for California businesses and residents that we were not able to quantify. Reduced prescribing volume for some non-preferred drugs – especially opioid analgesics – may lower rates of adverse events, drug-drug interactions, and, in the case of prescription opioid analgesics, potential misuse and abuse. These health benefits accrue to California residents and may have spillover effects on the broader economy.

C2. See comments for C1.

D. Alternatives to the regulation

D1. We considered two alternatives to the regulation. First, we estimated the costs and benefits of a similar formulary regulation but without the "special fill" provisions exempting some non-preferred drugs from prospective review in first fill and perioperative scenarios. The estimated costs were slightly higher in this case because more physician-dispensed fills were subject to prospective review. Overall the special fill provisions help ensure access to drugs shortly after injury and around surgical procedures without significantly changing the estimated costs or benefits from the regulation.

The second alternative was to adopt a formulary similar to one used in another state, such as the formulary used in Washington, Ohio, or Texas. We identified several reasons why these formularies would not fit the specific needs for a formulary in the California workers' compensation system, and therefore did not analyze benefits and costs of those alternatives. The Department's consultant RAND conducted a study to evaluate the options for the California workers' compensation formulary, including assessing the formularies in Washington, Ohio, and Texas. The study emphasized the need for the formulary to be consistent with the California treatment guidelines, which are primarily based on the guidelines of the American College of Occupational and Environmental Medicine (ACOEM). RAND indicated that the methods used to develop the ACOEM guidelines are more rigorous, but urged California to adopt updated versions of the guidelines[3]. DWC decided to proceed with using ACOEM guidelines to maintain consistency with the DWC's MTUS, which is primarily based on ACOEM guidelines and is moving to adopt updated guidelines and a formulary based on those guidelines.

D3. See comments for D1.

E. Major regulations

E5. See comments for C1.

[3] http://www.rand.org/content/dam/rand/pubs/research_reports/RR1500/RR1560/RAND_RR1560.pdf

Fiscal Impact Statement:

A. **Fiscal effect on local government**

A3. We assumed that public self-insured employers account for approximately 15% of total drug spending based on the overall share of workers' compensation costs for these employers (see http://www.dir.ca.gov/chswc/Reports/2015/CHSWC_AnnualReport2015_4.pdf, page 36). The resulting local government share of total savings from lower premiums is $3,443,000.

B. **Fiscal effect on state government**

B2. We assumed that the State of California accounts for 3.5% of total prescription drug spending based on the overall share of injured workers who are state employees. This share of total estimated direct premium savings is $803,000 in the first 12 months after the regulation is fully implemented.