

**ECONOMIC AND FISCAL IMPACT STATEMENT
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

ECONOMIC IMPACT STATEMENT

DEPARTMENT NAME CalRecycle	CONTACT PERSON Jason.Smyth@calrecycle.ca.gov	EMAIL ADDRESS Jason Smyth	TELEPHONE NUMBER (916) 341-6676
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400 Pharmaceutical and Sharps Recovery Stewardship Program Regulations			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:

- | | |
|--|---|
| <input checked="" type="checkbox"/> a. Impacts business and/or employees | <input checked="" type="checkbox"/> e. Imposes reporting requirements |
| <input checked="" type="checkbox"/> b. Impacts small businesses | <input type="checkbox"/> f. Imposes prescriptive instead of performance |
| <input checked="" type="checkbox"/> c. Impacts jobs or occupations | <input checked="" type="checkbox"/> g. Impacts individuals |
| <input type="checkbox"/> d. Impacts California competitiveness | <input type="checkbox"/> 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.*

CalRecycle2. The _____ estimates that the economic impact of this regulation (which includes the fiscal impact) is:
(Agency/Department)

- ☐ Below \$10 million
- ☐ Between \$10 and \$25 million
- ☒ 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: 6,600Describe the types of businesses (Include nonprofits): Primarily pharmacies and manufacturers of drugs and sharps. See Appendix.Enter the number or percentage of total businesses impacted that are small businesses: 90%4. Enter the number of businesses that will be created: 5 to 10 eliminated: NoneExplain: New non-profit stewardship organizations and miscellaneous others. See Appendix.5. Indicate the geographic extent of impacts: ☒ Statewide
☐ Local or regional (List areas): Excludes existing local programs. See Appendix.6. Enter the number of jobs created: ~40 and eliminated: 0 to 40Describe the types of jobs or occupations impacted: ~40 additional jobs added in the pharmaceutical industry and state government. See Appendix.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 ☒ 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? \$ 21.1 M annually
- a. Initial costs for a small business: \$ Minimal Annual ongoing costs: \$ Minimal Years: Ongoing
- b. Initial costs for a typical business: \$ 20k Pharma, 66k Sharps Annual ongoing costs: \$ 18k P., 61k Sharps Years: Ongoing
- c. Initial costs for an individual: \$ 0.25 P., \$10.75 Sharps Annual ongoing costs: \$ 0.22 P., \$13 Sharps Years: Ongoing
- d. Describe other economic costs that may occur: See Appendix for an explanation of cost estimates.
2. If multiple industries are impacted, enter the share of total costs for each industry: Initial cost for sharps: \$13.2 M; ongoing for sharps: \$12.2 M.
Initial cost for pharma: \$9.8 M; ongoing for pharma: \$8.9 M.
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. \$ See Appendix.
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: No Federal regulations are comparable to the
proposed regulations, which are necessary to clarify procedures for the Department to enforce SB 212.
Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: \$ N/A

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: The regulation will reduce the in-home and environmental impacts of unused pharmaceuticals and used sharps. This will reduce the public agency costs of managing expired, excess, and waste pharmaceuticals and sharps, and lead to several public health benefits. See Appendix.
2. Are the benefits the result of: ☒ specific statutory requirements, or ☐ goals developed by the agency based on broad statutory authority?
Explain: The Department is developing the regulation as required per SB 212.
3. What are the total statewide benefits from this regulation over its lifetime? \$ Qualitative. See Appendix.
4. Briefly describe any expansion of businesses currently doing business within the State of California that would result from this regulation: Medical waste haulers, reverse-distributors, and disposal facilities may see increased demand, as will businesses that produce sharps containers and pharmaceutical kiosks, and some ad agencies, legal firms, and other administrative service providers.

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: Alt. 1: Require all purchasers of sharps to be given a container and mail-back materials for the same quantity bought, resulting in greater cost. Alt. 2: Lessen accessibility standards for education and outreach materials, lowering cost but also consumer participation. See Appendix.

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ECONOMIC IMPACT STATEMENT (CONTINUED)

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

Regulation: Benefit: \$ 5.0 M/year Cost: \$ 21.1 M/yearAlternative 1: Benefit: \$ 5.0 M/year Cost: \$ 114 M/yearAlternative 2: Benefit: \$ 5.0 M/year Cost: \$ 20.3 M/year

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

See Appendix.

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☒ NOExplain: This regulation does not mandate the use of specific equipment.**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: Require sharps retailers to provide a sharps container for each corresponding sharps sale.Alternative 2: Require lower level of ADA compliance for education & outreach materials produced by Stewardship Org.*(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 \$ 21.1 M/year Cost-effectiveness ratio: \$ 5,000/tonAlternative 1: Total Cost \$ 114 M/year Cost-effectiveness ratio: \$ 30,000/tonAlternative 2: Total Cost \$ 20.3 M/year Cost-effectiveness ratio: \$ 5,400/ton

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 through 12 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: There may be some investment in medical waste hauling services and disposal facilities, although the state already has sufficient infrastructure capacity to manage the additional waste collected.The incentive for innovation in products, materials or processes: No incentive for innovation has been identified.

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 Part C.1.

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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)

\$ _____

- ☐ 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 Counties that are currently paying for the transportation and disposal of sharps waste collected at HHW
facilities will see a direct cost savings through reimbursement from the stewardship programs.

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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)\$ \$1.5 M. See Appendix.*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)

\$ _____

☐ 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



10/15/19

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



11.22.19

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

