

15. STD Form 399 and Appendix

The forms included in this section has been signed by the following individuals

- a. Form 399 and Appendix: submitted with Notice of Proposed Action

Olga Garti – Staff Services Manager III, Fiscal Officer

Jared Blumenfeld – Secretary for Environmental Protection Agency

- b. Revised Form 399 and Appendix: noticed for public comment on 8/21/2020

Olga Garti – Staff Services Manager III, Fiscal Officer

Eric Jarvis – Deputy Secretary for Fiscal and Administrative Programs, Environmental Protection Agency

Teresa Calvert – Department of Finance

**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.*

CalRecycle

2. 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: _____

**ECONOMIC AND FISCAL IMPACT STATEMENT
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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 NOExplain 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.

**ECONOMIC AND FISCAL IMPACT STATEMENT
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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/year
 Alternative 1: Benefit: \$ 5.0 M/year Cost: \$ 114 M/year
 Alternative 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/ton
 Alternative 1: Total Cost \$ 114 M/year Cost-effectiveness ratio: \$ 30,000/ton
 Alternative 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.

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

STD. 399 (REV. 12/2013)

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.

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

STD. 399 (REV. 12/2013)

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



STD. 399, ECONOMIC AND FISCAL IMPACT STATEMENT
Regulation Implementing SB212

Part A. ESTIMATED PRIVATE SECTOR COST IMPACTS

A.3. Total Number of Businesses Impacted

CalRecycle staff estimate that approximately 500 pharmaceutical manufacturers and 200 sharps manufacturers sell covered products in California. Under SB 212, these manufacturers are considered the “covered entities” responsible for funding and implementing a stewardship program for the covered products they sell, either individually or collectively, through a non-profit “stewardship organization” (see A.4., below). While the bulk of the financial impact of the regulation will be incurred by these covered entities, any business that sells sharps in a California county that is not already subject to a local sharps disposal ordinance (most retail pharmacies) will be responsible for distributing pre-paid sharps containers and mail-back materials to its customers on behalf of the covered entities, and will also have certain recordkeeping requirements. Many retail pharmacies in California will also work with stewardship organizations to host pharmaceutical collection kiosks, but it is assumed that the number of pharmaceutical collections sites will be a subset of, not an addition to, the number of pharmacies required to distribute sharps mail-back containers.

Retail pharmacies in California will be directly impacted by the regulation and will incur costs associated with recordkeeping, occasional reporting to the department, and distributing sharps containers, which are estimated to cost a combined total of \$100,000 per year, split among all the pharmacies. One of the reasons these cost are relatively small is that retail pharmacies are anticipated to fulfill the recordkeeping requirements at the corporate level instead of incurring recordkeeping costs at each individual pharmacy. Data from the State Board of Pharmacy¹ indicate that there are approximately 6,500 retail pharmacies in California, 10% of which are located in a county that is already subject to a local sharps ordinance, and most of which are considered small businesses as they employ fewer than 100 workers². Thus, it is estimated that 5,850 retail pharmacies will be directly impacted by the regulation.

Furthermore, certain waste haulers, disposal facilities, manufacturers of sharps containers and pharmaceutical kiosks, and certain advertising agencies associated with the stewardship organization’s education and outreach efforts will see an increase in business activity as an indirect result of the regulation.

In total, the department estimates that 6,600 California businesses will be impacted by the regulation, although the extent of this impact varies considerably depending on the type of business and the number of stewardship programs that are ultimately implemented.

A.4. Businesses Created

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profits, per statutory requirements) to administer the stewardship programs. A small expansion in waste hauling and disposal is also expected, which might lead to additional businesses being created, but is more likely to result in expansion of existing businesses.

A.5. Geographic Extent of Impacts

The impacts of the regulation will be statewide; however, the nine counties with existing programs for the collection of home-generated pharmaceutical waste (Alameda, Contra Costa, Marin, San Francisco, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, and Santa Cruz) and the four counties with local programs for sharps (Alameda, San Luis Obispo, Santa Clara, and Santa Cruz) have indicated they will continue their local program and are unlikely to be impacted by the statewide program.

A.6. Jobs Created

Approximately 40 new jobs will be created statewide as a direct result of the regulation. This number includes 17 new jobs for CalRecycle and the State Board of Pharmacy, with the remainder being jobs in newly-formed stewardship organizations. In order to calculate potential job loss, staff had to consider how much of the costs to operate the stewardship programs may be passed on to consumers through retail price increases. It is important to note that statute requires stewardship plans demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities. However, determining whether a change in retail prices for the thousands of covered products in the marketplace will occur as a result of the regulation or the number of the other factors that go into a manufacturer's determination of product price will be exceedingly difficult, if not impossible. Therefore, although it is expected that manufacturers will not increase prices consistent with the law, staff ran the REMI economic model under three different assumptions regarding how much of program costs may be passed on to consumers in order to prepare as conservative an economic analysis as possible. Under the most conservative assumption that 100% of the program costs could be passed on to consumers, around 40 jobs are expected to be lost, resulting in a total net job loss of 0 due to the 40 new jobs that are created as discussed above. See Table 1 below.

Table 1: REMI Model Economic Output

Output Statistic	Level of Consumer Cost Pass-Through		
	0%	50%	100%
Multiplier	0.518	0.199	0.024
State GPD Change	\$8.3 M	\$3.2 M	\$389k
Total Net Employment Change	90	20	0
Personal Income Change	\$9.2 M	\$2.9 M	\$2.1 M

Part B. ESTIMATED COSTS**B.1.a-b. Financial Impact on Businesses**

The financial impact on a business as a result of the regulation will vary depending on the size and nature of the business. As mentioned in Part A, the costs for a retail pharmacy are minimal. The manufacturers of pharmaceuticals and sharps that are responsible for funding the program are primarily large businesses but may also include some small businesses that manufacture niche products. While the regulation does not specify how the costs of the program should be allocated between the entities participating in a stewardship organization, it is anticipated that costs will be allocated in proportion to the quantity of covered pharmaceuticals or sharps the manufacturer sells in California. This assumption is consistent with producer responsibility programs in operation elsewhere which utilize a sales-based formula to determine each manufacturer's financial obligation. The result is that large manufacturers will pay a greater proportion of the implementation costs than the smaller manufacturers.

There are approximately 700 covered entities that will bear nearly all of the direct costs of the regulation, of which approximately 500 are pharmaceutical manufacturers and 200 are sharps manufacturers. CalRecycle estimates that the initial cost for the statewide pharmaceutical program is approximately \$9.8 million, or \$20,000 for each of the pharmaceutical manufacturers. These costs include administration, outreach and education, and installation of pharmaceutical kiosks at approximately 750 pharmacies statewide. The ongoing annual cost is estimated to be \$8.9 million, or \$18,000 per pharmaceutical manufacturer, which includes administration, outreach and education, collection and disposal of pharmaceuticals at kiosks, and installation of additional pharmaceutical kiosks each year.

CalRecycle estimates that the initial cost for the statewide sharps program is approximately \$13.2 million, or \$66,000 per sharps manufacturer. These costs include administration, outreach and education, mail-back containers, collection and disposal of sharps, and installation of sharps kiosks at approximately 850 pharmacies statewide. The ongoing annual cost is \$12.2 million, or \$61,000 per

sharps manufacturer, which includes administration, outreach and education, mail-back containers and mail-back costs, collection and disposal of sharps, and installation of additional sharps kiosks each year to supplement the mandatory mail-back requirement.

The cost estimates above are based on a number of data sources and assumptions regarding program implementation. An overview of the major cost categories and the components of each category is listed below.

- 1) Administrative costs. These costs include the administrative fees paid to CalRecycle and the Board of Pharmacy by the covered entities. The cost estimates are based on existing data from CalRecycle's mattress EPR program³, which has similar requirements to the pharmaceutical and sharps program.
- 2) Outreach and education. A total estimated cost of \$3.3 million was determined by examining data from CalRecycle's mattress program³, as existing reports from local jurisdictions with similar programs for pharmaceuticals and/or sharps do not disclose education and outreach costs.
- 3) Pharmaceutical kiosks. CalRecycle obtained data from the New York State Department of Environmental Conservation's Pharmaceutical Take Back Pilot Program⁴ which indicated that an individual 50-gallon pharmaceutical kiosk costs \$1,250. Population data for California counties⁵ was then used to calculate the number of pharmaceutical kiosks needed to meet the minimum convenience standards prescribed in statute and estimate the total costs for these kiosks. The department also incorporated demographic trends⁶ into its analysis, as the required number of kiosks will increase as the state's population grows over time.
- 4) Pharmaceutical collection and disposal. CalRecycle obtained data from Santa Clara County's Safe Drug Disposal Program⁷ which indicates that the cost of "servicing" a pharmaceutical kiosk is on average \$333 per service, which includes the costs of collecting, transporting, and properly disposing of the collected material. The department's analysis assumes that pharmaceutical kiosks will be serviced once per month, which is an appropriate average for a statewide program that covers both dense urban areas and sparsely-populated rural ones.
- 5) Sharps mail-back. The department obtained data from Sharps Compliance, Inc⁸. on container costs, consumer habits, and the extent of the current sharps mail-back market in order to generate a model of the statewide sharps program. The department's model starts with the baseline number of sharps mail-back containers currently distributed, and increases this number over time as the program matures. The model also contains variables to represent consumer behavior, which has a major impact on program costs as a container that is actually mailed back costs an order of magnitude more than a container that is not. Thus, the model anticipates that 60% of consumers will mail back their free sharps container, while the other 40% will dispose of the container through sharps kiosks or other means, as described below. The department

finds this modeling approach reasonable, if not conservative, as a significant portion of sharps users currently dispose of their sharps in the household trash, at a household hazardous waste facility, or in a sharps kiosk, and may continue to do so even after implementation of the statewide sharps mail-back program.

- 6) Sharps kiosks. While not required by the regulation, this option is used widely among existing programs as there is a significant financial incentive to supplement the mandatory sharps mail-back program with sharps kiosks for the reasons described above. This would also increase the number of convenient, proper disposal options available to consumers. CalRecycle obtained data from the Tehama County Medical Waste Sharps Collection Program⁹ regarding the cost per kiosk and the associated monthly servicing cost, and assumed a similar number of sharps kiosks as pharmaceutical kiosks will be installed throughout the state, as collection sites that are suitable to collect pharmaceuticals will likely also be suitable to collect sharps.

B.1.c. Financial Impact on Individuals

As discussed above in A.6., although statute states that all administrative and operational costs of the programs are to be borne by covered entities, the regulation cannot ensure that pharmaceutical and sharps manufacturers will not raise the retail price of products in order to pass on to consumers the increased costs of compliance with SB 212. In order to most conservatively capture the range of potential impacts on individuals due to price increases, the REMI economic model was run with different levels of consumer-cost pass-through (Table 1). Under the most conservative assumption that 100% of program costs are passed on to consumers, the costs per individual in California (assuming all Californians use covered drugs at least once per year) for the pharmaceutical program would be approximately 25 cents for initial program costs and 22 cents annually thereafter. And under this scenario, the costs for the sharps program would be approximately \$10.75 per sharps user (roughly 920,000 in California⁷) initially, and \$13.30 annually thereafter.

After accounting for the indirect and induced effects of the regulation on the overall economy, the aggregate projected State GDP growth in 2024 (the highest cost year) was between \$389,000 and \$8.3 million, depending on whether 100% or 0% of program costs were passed on to consumers, respectively. Similarly, total State Personal Income in 2024 was projected to grow between \$2.1 million and \$8.9 million, depending on whether 100% or 0% of program costs were passed on to consumers, respectively.

B.3. Annual Typical Business Cost if Regulation Imposes Reporting Requirements

The regulation requires a covered entity or stewardship organization operating on behalf of a group of covered entities to submit an annual report to CalRecycle containing detailed information regarding its activities pursuant to the approved stewardship plan over the previous reporting period. Preparation of these reports will incur costs for the stewardship organization as it requires a comprehensive review of performance during the reporting period and involves coordination

between the covered entity or stewardship organization and other private businesses or contractors associated with program implementation.

Furthermore, the regulation will require retail pharmacies, or a corporate officer acting on behalf of a retail pharmacy chain, to monitor CalRecycle's website for updates to the lists of covered entities and stewardship organizations in compliance with the regulation. If the retail pharmacy or retail pharmacy chain discovers that it is offering for sale any covered products from manufacturers that are out of compliance, it is required to notify the department. The costs associated with this reporting requirement are included in the \$100,000 cost estimate discussed in A.3.

By examining similar costs associated with preparing annual reports from CalRecycle's mattress stewardship program², the total cost of these efforts are approximately \$1-2 million per year and will be distributed among the roughly 700 covered entities that will participate in the program.

Part C. ESTIMATED BENEFITS

C.1. and C.3. Discussion of Statewide Benefits

CalRecycle has determined that the proposed regulation will result in benefits to public health and the environment. These benefits are discussed qualitatively as data limitations prohibit a quantitative analysis of the benefits. For example, California is estimated to spend \$4 million annually due to needle-stick injuries, based on applying a ratio of California's population to a national data set⁹ that estimated the national cost of needle-stick injuries. Some subset of these needle-stick injuries are due to home-generated sharps waste that has been improperly disposed of, and these injuries are likely to decrease due to the regulation. However, the proportion of injuries that are caused by improper disposal and the number of injuries that would be prevented due to the regulation are impossible to estimate with any degree of confidence. Given these types of data limitations, the four areas where public health or environmental benefits will be realized as a result of the regulation are discussed qualitatively below.

- 1) Reduction of needle-stick injuries. Every year, California workers in waste facilities and sanitation services, as well as members of the general public, are injured by hypodermic needles that have been improperly disposed of in the household trash or in public places such as parks or beaches. Needle-stick injuries often result in time taken off of work and expensive testing for infectious disease¹⁰. By providing consumers with safe and convenient disposal methods for used sharps, the regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs.
- 2) Reduction of accidental poisonings. Unused medications in the household are known to pose a health risk to children and pets if accidentally ingested¹¹. By providing consumers with convenient disposal options and conducting education and outreach campaigns to encourage their use, the regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications.

- 3) Reduction in abuse of prescription drugs. The stockpiling of dangerous and highly addictive prescription drugs such as opioids in household medicine cabinets is a contributor to prescription drug abuse¹². California is estimated to spend billions of dollars every year as a result of prescription drug abuse¹³, and this regulation may contribute to a reduction in the abuse of prescription drugs.
- 4) Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of in a sink or toilet¹⁴. Even in trace amounts, pharmaceutical compounds are known to have adverse effects on human embryonic cells as well as fish populations and other organisms, and may already be impacting public and environmental health¹⁵. By diverting household pharmaceutical waste toward proper disposal methods, the regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water.

Part D. ALTERNATIVES TO THE REGULATION

D.1. Analysis of Regulatory Alternatives

Alternative 1

Alternative 1 is to clarify in regulation the phrase “provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale” to mean that every customer is given a sharps container and mail-back materials at each individual sale sufficient to accommodate the volume of sharps purchased. However, some customers who purchase syringes (and associated medications) on a frequent and routine basis may prefer not to receive a sharps container every time they purchase sharps. For example, a self-injector may prefer to receive a 1-gallon sharps container which could accommodate the amount of sharps they use over the course of nine months and enable them to make multiple purchases of syringes without incurring the additional burden of receiving and transporting a sharps container during that period of time.

Alternative 1 may also create a burden on pharmacies that have limited floor space to store sharps containers. Alternative 1 is estimated to cost covered entities \$114 million per year, which exceeds the cost of the regulation (\$21.1 million per year) and is not anticipated to result in significantly more sharps collected from ultimate users.

Alternative 1 was not selected as it does not significantly increase the quantity of sharps that would be collected and is more costly than the proposed regulation.

Alternative 2

The proposed regulation requires that education and outreach materials produced by a stewardship organization are held to at least the same accessibility standards used by CalRecycle on its internet website. These accessibility standards include provisions for visually or hearing impaired individuals, availability of text translations for several different languages, and full ADA compliance. A lower cost alternative would not require all education and outreach materials to meet accessibility standards. Under Alternative 2, stewardship organizations would save thousands of

dollars per year in printing, translation, and IT costs, but the education and outreach campaigns would be less successful in reaching certain communities and target audiences. Consequently, Alternative 2 would result in less pharmaceutical and sharps waste collected and reduce the effectiveness of the law, which is why it was not selected.

D.2 & D.3. Quantification Issues Relevant to the Cost/Benefit Analysis of the Alternatives

The regulation will result in savings to consumers and local governments as the cost of purchasing sharps mail-back containers and disposing of unused pharmaceuticals will shift from local governments and consumers to industry. Under the regulation, mail-back containers and the cost of shipping and disposal will be paid for by the sharps manufacturers. Statewide there will be a direct cost savings of about \$4 million per year as consumers will no longer need to purchase mail-back containers. There will also be savings of approximately \$500,000 annually to local government household hazardous waste (HHW) programs. Under the regulation, sharps manufacturers will either pay for or reimburse counties for the transportation and disposal of sharps at HHW collection sites. Counties that are currently paying for transportation and disposal of sharps collected at HHW sites will see a direct cost savings from this shift. Finally, there will be a reduction in the amount of waste that is sent to landfills, which will result in reduced landfill tipping fees of about \$42f,000 per year.

Under Alternatives 1 and 2, the overall net benefits would be about the same as the regulation – approximately \$5.0 million per year.

FISCAL IMPACT STATEMENT

Part B. FISCAL EFFECT ON STATE GOVERNMENT

In Fiscal Year 2019-20, CalRecycle and the Board of Pharmacy staff costs to develop the regulation and oversee its implementation will total \$1,518,100. Costs for the state are expected to increase in subsequent years as additional enforcement staff are hired to ensure that regulated entities are in compliance. Starting in 2023, the State's costs associated with SB 212 (including costs incurred prior to 2023) will be reimbursed by covered entities participating in stewardship programs. Department costs to oversee implementation of SB 212 prior to reimbursement will be covered by a loan from CalRecycle's E-Waste program.

Citations

- ¹ “License Type Totals,” *the California State Board of Pharmacy*, July 2, 2019. https://www.pharmacy.ca.gov/about/license_total.shtml.
- ² Subsection (1)(A) of Subdivision (d) of Section 14837 of the Government Code.
- ³ “2017 California Annual Report,” *Mattress Recycling Council California, LLC*, July 1, 2018, pp. 46, 48.
- ⁴ Snow, Thomas <Thomas.Snow@dec.ny.gov>, “Pharmaceutical Kiosk Pricing Information,” April 23, 2019, office communication.
- ⁵ “California County Population Estimates and Components of Change by Year, July 1, 2010-2018,” *State of California, Department of Finance, E-2*. Sacramento, California, December 2018.
- ⁶ “Population Projections (Baseline 2016),” *State of California, Department of Finance*, Sacramento, California, January 2018.
- ⁷ Grimes, William <William.Grimes@cep.sccgov.org>, “EPR PharmaSharps – Form 303 and Budget/Cost Information for EPR Program,” September 27, 2018, office communication.
- ⁸ Lingner, Wanda <Wlingner@sharpsinc.com>, “Sharps Mailback Program Economics,” March 28, 2019, office communication.
- ⁹ Ross, Rachel, <RRoss@co.tehama.ca.us>, “Tehama County Pharmaceutical Drug and Medical Waste Sharps Collection Program,” November 05, 2018, office communication.
- ¹⁰ Leigh, J. P., Wiatrowski, W. J., Gillen, M., & Steenland, N. K., “Characteristics of persons and jobs with needlestick injuries in a national data set,” *American journal of infection control*, 2008, 36(6), 414-420.
- ¹¹ Bond, G. R., Woodward, R. W., & Ho, M., “The growing impact of pediatric pharmaceutical poisoning,” *The Journal of Pediatrics*, 2012, 160(2), 265-270.
- ¹² Kennedy-Hendricks A, Gielen A, McDonald E, McGinty EE, Shields W, Barry CL., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” *JAMA Internal Medicine*. 2016, 176(7):1027–1029.
- ¹³ Florence, C., Luo, F., Xu, L., & Zhou, C., “The economic burden of prescription opioid overdose, abuse and dependence in the United States 2013,” *Medical care*, 2016, 54(10), 901.
- ¹⁴ Stackelberg, P. E., Furlong, E. T., Meyer, M. T., Zaugg, S. D., Henderson, A. K., & Reissman, D. B., “Persistence of pharmaceutical compounds and other organic wastewater contaminants in a conventional drinking-water-treatment plant,” *Science of the Total Environment*, 2004, 329(1-3), 99-113.

- ¹⁵ Ferrey, M., “Pharmaceuticals and endocrine active chemicals in Minnesota Lakes,” *Minnesota Pollution Control Agency*, May 2013.
<https://www.pca.state.mn.us/sites/default/files/tdr-g1-16.pdf>.

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

STD. 399 (Rev. 10/2019)

ECONOMIC IMPACT STATEMENT

DEPARTMENT NAME CalRecycle	CONTACT PERSON Jason Smyth	EMAIL ADDRESS Jason.Smyth@CalRecycle.ca.gov	TELEPHONE NUMBER (916) 341-6676
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400 Pharmaceutical and Sharps Waste Stewardship Program			NOTICE FILE NUMBER Z 2019-1223-02

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:

- a. Impacts business and/or employees e. Imposes reporting requirements
 b. Impacts small businesses f. Imposes prescriptive instead of performance
 c. Impacts jobs or occupations g. Impacts individuals
 d. Impacts California competitiveness 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.***CalRecycle**2. The CalRecycle 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: ~50 and eliminated: 0Describe the types of jobs or occupations impacted: ~50 additional jobs directly added in the pharmaceutical industry and state government. Additional jobs added in state economy due to indirect effects of the regulation. 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 NOIf YES, explain briefly: _____

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

STD. 399 (Rev. 10/2019)

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? \$ 22.1 M annually
- a. Initial costs for a small business: \$ Minimal Annual ongoing costs: \$ Minimal Years: Ongoing
- b. Initial costs for a typical business: \$ 25k Pharma, 67k Sharps Annual ongoing costs: \$ 19k P., 64k Sharps Years: Ongoing
- c. Initial costs for an individual: \$ 0.31 P., \$14.66 Sharps Annual ongoing costs: \$ 0.24 P., \$14 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: \$13.5 M; ongoing for sharps: \$12.7 M. Initial cost for pharma: \$12.3 M; ongoing for pharma: \$9.4 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.

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

STD. 399 (Rev. 10/2019)

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: \$ 22.1 M/year
 Alternative 1: Benefit: \$ 5.0 M/year Cost: \$ 115 M/year
 Alternative 2: Benefit: \$ 5.0 M/year Cost: \$ 21.3 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 technologies or equipment, and does not prescribe specific actions or procedures.**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: Do not include language or accessibility requirements for Stewardship Program materials and website.

(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 \$ 22.1 M/year Cost-effectiveness ratio: \$ 5,324/ton
 Alternative 1: Total Cost \$ 115 M/year Cost-effectiveness ratio: \$ 30,771/ton
 Alternative 2: Total Cost \$ 21.3 M/year Cost-effectiveness ratio: \$ 5,740/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.

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

STD. 399 (Rev. 10/2019)

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.

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

STD. 399 (Rev. 10/2019)

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)\$ 2.7 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

9/16/2020

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

9/16/20

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

11/17/2020

STD. 399, ECONOMIC AND FISCAL IMPACT STATEMENT Regulation Implementing SB212

Part A. ESTIMATED PRIVATE SECTOR COST IMPACTS

A.3. Total Number of Businesses Impacted

By examining existing stewardship programs for pharmaceuticals and home-generated sharps waste, CalRecycle staff estimate that approximately 500 pharmaceutical manufacturers and 200 sharps manufacturers sell covered products in California. Under SB 212, these manufacturers are considered the “covered entities” responsible for funding and implementing a “stewardship program” for the covered products they sell, either individually or collectively, through a non-profit “stewardship organization” (see A.4., below).

While the bulk of the financial impact of the regulation will be incurred by these covered entities, any business that sells sharps in a California county that is not already subject to a local sharps disposal ordinance (most retail pharmacies) will need to coordinate with covered entities and/or stewardship organizations (collectively referred to as “program operators”) to distribute pre-paid sharps containers and mail-back materials to its customers. Through this process, retail pharmacies may incur costs associated with storing sharps containers and distributing them to consumers. However, the proposed regulations give program operators the flexibility to design distribution mechanisms that uphold consumer convenience while being minimally burdensome, and may or may not even involve on-site storage of sharps containers. Thus, these costs incurred by retail pharmacies depend on negotiations with program operators and are expected to be minimal. Many retail pharmacies in California will also work with program operators to host pharmaceutical collection kiosks and incur minimal costs associated with logistics and floor space, but it is assumed that the number of pharmaceutical collections sites will be a subset of, not an addition to, the number of pharmacies required to distribute sharps mail-back containers. Retail pharmacies in California will also incur costs associated with recordkeeping and occasional reporting to the department, which are estimated to cost a combined total of \$100,000 per year, split among all the pharmacies. One of the reasons these costs are relatively small is that retail pharmacies are anticipated to fulfill the recordkeeping requirements at the corporate level instead of incurring recordkeeping costs at each individual pharmacy.

Data from the State Board of Pharmacy¹ indicate that there are approximately 6,500 retail pharmacies in California, 10% of which are located in a county that is already subject to a local sharps ordinance, and most of which are considered small businesses as they employ fewer than 100 workers². Thus, it is estimated that 5,850 retail pharmacies will be directly impacted by the regulation.

Furthermore, certain waste haulers, disposal facilities, manufacturers of sharps containers and pharmaceutical kiosks, and certain advertising agencies associated with the stewardship organization’s education and outreach efforts will see an increase in business activity as an indirect result of the regulation.

In total, the department estimates that 6,600 California businesses will be impacted by the regulation, although the extent of this impact varies considerably depending on the type of business and the number of stewardship programs that are ultimately implemented.

A.4. Businesses Created

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profits, per statutory requirements) to administer the stewardship programs. A small expansion in waste hauling and disposal is also expected, which might lead to additional businesses being created, but is more likely to result in expansion of existing businesses.

A.5. Geographic Extent of Impacts

The impacts of the regulation will be statewide; however, the nine counties with existing programs for the collection of home-generated pharmaceutical waste (Alameda, Contra Costa, Marin, San Francisco, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, and Santa Cruz) and the four counties with local programs for sharps (Alameda, San Luis Obispo, Santa Clara, and Santa Cruz) have indicated they will continue their local program and are unlikely to be impacted by the statewide program.

A.6. Jobs Created

Approximately 50 new jobs will be created statewide as a direct result of the regulation. This number includes 24 new jobs for CalRecycle and the State Board of Pharmacy, with the remainder being jobs in newly-formed stewardship organizations. In order to calculate potential changes in employment due to indirect effects of the regulation, staff had to consider how much of the costs to operate the stewardship programs may be passed on to consumers through retail price increases. It is important to note that statute requires stewardship plans demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities. However, determining whether a change in retail prices for the thousands of covered products in the marketplace will occur as a result of the regulation or the number of the other factors that go into a manufacturer's determination of product price will be exceedingly difficult, if not impossible. Therefore, although it is expected that manufacturers will not increase prices consistent with the law, staff ran the REMI economic model under three different assumptions regarding how much of program costs may be passed on to consumers in order to prepare as conservative an economic analysis as possible. Under the most conservative assumption that 100% of the program costs could be passed on to consumers, around 7 jobs are expected to be gained, resulting in a total net job gain of 57 due to the 50 new jobs that are directly created as discussed above. See Table 1 below.

Table 1: REMI Model Economic Output

	Level of Consumer Cost Pass-Through		
Output Statistic	0%	50%	100%
Multiplier	0.597	0.386	0.066
State GPD Change	\$10.3 M	\$6.6 M	\$1.1 M
Total Net Employment Change (Direct* + Indirect Job Gains)	165 (50+115)	118 (50+68)	57 (50+7)
Personal Income Change	\$11.7 M	\$8.1 M	\$3.0 M

*Direct job gains calculated by CalRecycle, as described in section A.6. above

Part B. ESTIMATED COSTS

B.1.a-b. Financial Impact on Businesses

The financial impact on a business as a result of the regulation will vary depending on the size and nature of the business. As mentioned in Part A, the costs for a retail pharmacy are minimal. The manufacturers of pharmaceuticals and sharps that are responsible for funding the program are primarily large businesses but may also include some small businesses that manufacture niche products. While the regulation does not specify how the costs of the program should be allocated between the entities participating in a stewardship organization, it is anticipated that costs will be allocated in proportion to the quantity of covered pharmaceuticals or sharps the manufacturer sells in California. This assumption is consistent with producer responsibility programs in operation elsewhere which utilize a sales-based formula to determine each manufacturer's financial obligation. The result is that large manufacturers will pay a greater proportion of the implementation costs than the smaller manufacturers.

There are approximately 700 covered entities that will bear nearly all of the direct costs of the regulation, of which approximately 500 are pharmaceutical manufacturers and 200 are sharps manufacturers. CalRecycle estimates that the initial cost for the statewide pharmaceutical program is approximately \$12.3 million, or \$25,000 for each of the pharmaceutical manufacturers. These costs include administration, outreach and education, CalRecycle and Board of Pharmacy fees for the rulemaking and stewardship plan review processes, and installation of pharmaceutical kiosks at approximately 750 pharmacies statewide. The ongoing annual cost is estimated to be \$9.4 million, or \$19,000 per pharmaceutical manufacturer, which includes administration, outreach and education, collection and disposal of pharmaceuticals at kiosks, and installation of additional pharmaceutical kiosks each year.

CalRecycle estimates that the initial cost for the statewide sharps program is approximately \$13.5 million, or \$67,000 per sharps manufacturer. These costs

include administration, outreach and education, CalRecycle and Board of Pharmacy fees for the rulemaking and stewardship plan review processes, mail-back containers, collection and disposal of sharps, and installation of sharps kiosks at approximately 850 pharmacies statewide. The ongoing annual cost is \$12.7 million, or \$64,000 per sharps manufacturer, which includes administration, outreach and education, mail-back containers and mail-back costs, collection and disposal of sharps, and installation of additional sharps kiosks each year to supplement the mandatory mail-back requirement.

The cost estimates above are based on a number of data sources and assumptions regarding program implementation. An overview of the major cost categories and the components of each category is listed below.

- 1) Administrative costs. These costs include the administrative fees paid to CalRecycle and the Board of Pharmacy by the covered entities. The cost estimates are based on existing data from CalRecycle's mattress EPR program³, which has similar requirements to the pharmaceutical and sharps program.
- 2) Outreach and education. A total estimated cost of \$3.3 million was determined by examining data from CalRecycle's mattress program³, as existing reports from local jurisdictions with similar programs for pharmaceuticals and/or sharps do not disclose education and outreach costs.
- 3) Pharmaceutical kiosks. CalRecycle obtained data from the New York State Department of Environmental Conservation's Pharmaceutical Take Back Pilot Program⁴ which indicated that an individual 50-gallon pharmaceutical kiosk costs \$1,250. Population data for California counties⁵ was then used to calculate the number of pharmaceutical kiosks needed to meet the minimum convenience standards prescribed in statute and estimate the total costs for these kiosks. The department also incorporated demographic trends⁶ into its analysis, as the required number of kiosks will increase as the state's population grows over time.
- 4) Pharmaceutical collection and disposal. CalRecycle obtained data from Santa Clara County's Safe Drug Disposal Program⁷ which indicates that the cost of "servicing" a pharmaceutical kiosk is on average \$333 per service, which includes the costs of collecting, transporting, and properly disposing of the collected material. The department's analysis assumes that pharmaceutical kiosks will be serviced once per month, which is an appropriate average for a statewide program that covers both dense urban areas and sparsely-populated rural ones.
- 5) Sharps mail-back. The department obtained data from Sharps Compliance, Inc⁸. on container costs, consumer habits, and the extent of the current sharps mail-back market in order to generate a model of the statewide sharps program. The department's model starts with the baseline number of sharps mail-back containers currently distributed, and increases this number over time as the program matures. The model also contains variables to represent consumer behavior, which has a major impact on program costs as a container

that is actually mailed back costs an order of magnitude more than a container that is not. Thus, the model anticipates that 60% of consumers will mail back their free sharps container, while the other 40% will dispose of the container through sharps kiosks or other means, as described below. The department finds this modeling approach reasonable, if not conservative, as a significant portion of sharps users currently dispose of their sharps in the household trash, at a household hazardous waste facility, or in a sharps kiosk, and may continue to do so even after implementation of the statewide sharps mail-back program.

- 6) Sharps kiosks. While not required by the regulation, this option is used widely among existing programs as there is a significant financial incentive to supplement the mandatory sharps mail-back program with sharps kiosks for the reasons described above. This would also increase the number of convenient, proper disposal options available to consumers. CalRecycle obtained data from the Tehama County Medical Waste Sharps Collection Program⁹ regarding the cost per kiosk and the associated monthly servicing cost, and assumed a similar number of sharps kiosks as pharmaceutical kiosks will be installed throughout the state, as collection sites that are suitable to collect pharmaceuticals will likely also be suitable to collect sharps.

B.1.c. Financial Impact on Individuals

As discussed above in A.6., although statute states that all administrative and operational costs of the programs are to be borne by covered entities, the regulation cannot ensure that pharmaceutical and sharps manufacturers will not raise the retail price of products in order to pass on to consumers the increased costs of compliance with SB 212. In order to most conservatively capture the range of potential impacts on individuals due to price increases, the REMI economic model was run with different levels of consumer-cost pass-through (Table 1). Under the most conservative assumption that 100% of program costs are passed on to consumers, the costs per individual in California (assuming all Californians use covered drugs at least once per year) for the pharmaceutical program would be approximately 31 cents for initial program costs and 24 cents annually thereafter. And under this scenario, the costs for the sharps program would be approximately \$14.66 per sharps user (roughly 920,000 in California⁷) initially, and \$13.83 annually thereafter.

After accounting for the indirect and induced effects of the regulation on the overall economy, the aggregate projected State GDP growth in 2024 (the highest cost year) was between \$389,000 and \$8.3 million, depending on whether 100% or 0% of program costs were passed on to consumers, respectively. Similarly, total State Personal Income in 2024 was projected to grow between \$2.1 million and \$8.9 million, depending on whether 100% or 0% of program costs were passed on to consumers, respectively.

B.3. Annual Typical Business Cost if Regulation Imposes Reporting Requirements

The regulation requires a program operator to submit an annual report to CalRecycle containing detailed information regarding its activities pursuant to the

approved stewardship plan over the previous reporting period. Preparation of these reports will incur costs for the program operator as it requires a comprehensive review of performance during the reporting period and involves coordination with other private businesses or contractors associated with program implementation.

Furthermore, the regulation will require retail pharmacies, or a corporate officer acting on behalf of a retail pharmacy chain, to monitor CalRecycle's website for updates to the lists of covered entities and stewardship organizations in compliance with the regulation. If the retail pharmacy or retail pharmacy chain discovers that it is offering for sale any covered products from manufacturers that are out of compliance, it is required to notify the department. The costs associated with this reporting requirement are included in the \$100,000 cost estimate discussed in A.3.

The total cost of these efforts are included in CalRecycle's estimate of roughly \$9 million in total annual administrative costs, based on a comparable annual report from the statewide mattress stewardship program³, and CalRecycle's current anticipated number of stewardship programs. These costs will be distributed among the roughly 700 covered entities that will participate in a stewardship program.

Part C. ESTIMATED BENEFITS

C.1. and C.3. Discussion of Statewide Benefits

CalRecycle has determined that the proposed regulation will result in benefits to public health and the environment. These benefits are discussed qualitatively as data limitations prohibit a quantitative analysis of the benefits. For example, California is estimated to spend \$4 million annually due to needle-stick injuries, based on applying a ratio of California's population to a national data set⁹ that estimated the national cost of needle-stick injuries. Some subset of these needle-stick injuries are due to home-generated sharps waste that has been improperly disposed of, and these injuries are likely to decrease due to the regulation. However, the proportion of injuries that are caused by improper disposal and the number of injuries that would be prevented due to the regulation are impossible to estimate with any degree of confidence. Given these types of data limitations, the four areas where public health or environmental benefits will be realized as a result of the regulation are discussed qualitatively below.

- 1) Reduction of needle-stick injuries. Every year, California workers in waste facilities and sanitation services, as well as members of the general public, are injured by hypodermic needles that have been improperly disposed of in the household trash or in public places such as parks or beaches. Needle-stick injuries often result in time taken off of work and expensive testing for infectious disease¹⁰. By providing consumers with safe and convenient disposal methods for used sharps, the regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs.
- 2) Reduction of accidental poisonings. Unused medications in the household are known to pose a health risk to children and pets if accidentally ingested¹¹. By

- providing consumers with convenient disposal options and conducting education and outreach campaigns to encourage their use, the regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications.
- 3) Reduction in abuse of prescription drugs. The stockpiling of dangerous and highly addictive prescription drugs such as opioids in household medicine cabinets is a contributor to prescription drug abuse¹². California is estimated to spend billions of dollars every year as a result of prescription drug abuse¹³, and this regulation may contribute to a reduction in the abuse of prescription drugs.
 - 4) Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of in a sink or toilet¹⁴. Even in trace amounts, pharmaceutical compounds are known to have adverse effects on human embryonic cells as well as fish populations and other organisms, and may already be impacting public and environmental health¹⁵. By diverting household pharmaceutical waste toward proper disposal methods, the regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water.

Part D. ALTERNATIVES TO THE REGULATION

D.1. Analysis of Regulatory Alternatives

Alternative 1

Alternative 1 is to clarify in regulation the phrase “provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale” to mean that every customer is given a sharps container and mail-back materials at each individual sale sufficient to accommodate the volume of sharps purchased.

However, some customers who purchase syringes (and associated medications) on a frequent and routine basis may prefer not to receive a sharps container every time they purchase sharps. For example, a self-injector may prefer to receive a 1-gallon sharps container which could accommodate the amount of sharps they use over the course of nine months and enable them to make multiple purchases of syringes without incurring the additional burden of receiving and transporting a sharps container during that period of time.

Alternative 1 may also create a burden on pharmacies that have limited floor space to store sharps containers. Alternative 1 is estimated to cost covered entities \$115 million per year, which exceeds the cost of the regulation (\$22.1 million per year) and is not anticipated to result in significantly more sharps collected from ultimate users.

Alternative 1 was not selected as it does not significantly increase the quantity of sharps that would be collected and is more costly than the proposed regulation.

Alternative 2

The proposed regulation requires that a program operator’s education and outreach activities and materials contain language translations suitable to local

demographics and certain considerations related to accessibility. Eliminating this requirement was considered as a lower cost Alternative 2. Under Alternative 2, a program operator would save thousands of dollars per year in printing, translation, and IT costs, but its education and outreach efforts would be less successful in reaching certain communities and target audiences. Consequently, Alternative 2 would result in less pharmaceutical and sharps waste collected and reduce the effectiveness of the law, which is why it was not selected.

D.2 & D.3. Quantification Issues Relevant to the Cost/Benefit Analysis of the Alternatives

The regulation will result in savings to consumers and local governments as the cost of purchasing sharps mail-back containers and disposing of unused pharmaceuticals will shift from local governments and consumers to industry. Under the regulation, mail-back containers and the cost of shipping and disposal will be paid for by the sharps program operator(s). Statewide there will be a direct cost savings of about \$4 million per year as consumers will no longer need to purchase mail-back containers. There will also be savings of approximately \$500,000 annually to local government household hazardous waste (HHW) programs. Under the regulation, sharps program operator(s) will either reimburse local jurisdictions or directly provide for the transportation and disposal of sharps from local HHW collection sites. Counties that are currently paying for transportation and disposal of sharps collected at HHW sites will see a direct cost savings from this shift. Finally, there will be a reduction in the amount of waste that is sent to landfills, which will result in reduced landfill tipping fees of about \$42,000 per year.

Under Alternatives 1 and 2, the overall net benefits would be about the same as the regulation – approximately \$5.0 million per year.

FISCAL IMPACT STATEMENT

Part B. FISCAL EFFECT ON STATE GOVERNMENT

In Fiscal Year 2020-21, CalRecycle and the Board of Pharmacy costs to develop the regulation and oversee its implementation total \$2,726,571, which is comprised of new staff salaries. Costs for the state are expected to increase in Fiscal Year 2021-22 as additional enforcement staff are hired to ensure that regulated entities are in compliance. Starting in 2023, the State's costs associated with SB 212 (including costs incurred prior to 2023) will be reimbursed by covered entities participating in stewardship programs. Department costs to oversee implementation of SB 212 prior to reimbursement will be covered by a loan from CalRecycle's E-Waste program.

Citations

- ¹ “License Type Totals,” *the California State Board of Pharmacy*, July 2, 2019. https://www.pharmacy.ca.gov/about/license_total.shtml.
- ² Subsection (1)(A) of Subdivision (d) of Section 14837 of the Government Code.
- ³ “2017 California Annual Report,” *Mattress Recycling Council California, LLC*, July 1, 2018, pp. 46, 48.
- ⁴ Snow, Thomas <Thomas.Snow@dec.ny.gov>, “Pharmaceutical Kiosk Pricing Information,” April 23, 2019, office communication.
- ⁵ “California County Population Estimates and Components of Change by Year, July 1, 2010-2018,” *State of California, Department of Finance, E-2*. Sacramento, California, December 2018.
- ⁶ “Population Projections (Baseline 2016),” *State of California, Department of Finance*, Sacramento, California, January 2018.
- ⁷ Grimes, William <William.Grimes@cep.sccgov.org>, “EPR PharmaSharps – Form 303 and Budget/Cost Information for EPR Program,” September 27, 2018, office communication.
- ⁸ Lingner, Wanda <Wlingner@sharpsinc.com>, “Sharps Mailback Program Economics,” March 28, 2019, office communication.
- ⁹ Ross, Rachel, <RRoss@co.tehama.ca.us>, “Tehama County Pharmaceutical Drug and Medical Waste Sharps Collection Program,” November 05, 2018, office communication.
- ¹⁰ Leigh, J. P., Wiatrowski, W. J., Gillen, M., & Steenland, N. K., “Characteristics of persons and jobs with needlestick injuries in a national data set,” *American journal of infection control*, 2008, 36(6), 414-420.
- ¹¹ Bond, G. R., Woodward, R. W., & Ho, M., “The growing impact of pediatric pharmaceutical poisoning,” *The Journal of Pediatrics*, 2012, 160(2), 265-270.
- ¹² Kennedy-Hendricks A, Gielen A, McDonald E, McGinty EE, Shields W, Barry CL., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” *JAMA Internal Medicine*. 2016, 176(7):1027–1029.
- ¹³ Florence, C., Luo, F., Xu, L., & Zhou, C., “The economic burden of prescription opioid overdose, abuse and dependence in the United States 2013,” *Medical care*, 2016, 54(10), 901.
- ¹⁴ Stackelberg, P. E., Furlong, E. T., Meyer, M. T., Zaugg, S. D., Henderson, A. K., & Reissman, D. B., “Persistence of pharmaceutical compounds and other organic wastewater contaminants in a conventional drinking-water-treatment plant,” *Science of the Total Environment*, 2004, 329(1-3), 99-113.

- ¹⁵ Ferrey, M., “Pharmaceuticals and endocrine active chemicals in Minnesota Lakes,” *Minnesota Pollution Control Agency*, May 2013.
<https://www.pca.state.mn.us/sites/default/files/tdr-g1-16.pdf>.