

**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 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 Pharmacy<sup>1</sup> 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 workers<sup>2</sup>. 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 program<sup>3</sup>, 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 program<sup>3</sup>, 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 Program<sup>4</sup> which indicated that an individual 50-gallon pharmaceutical kiosk costs \$1,250. Population data for California counties<sup>5</sup> 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 trends<sup>6</sup> 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 Program<sup>7</sup> 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, Inc<sup>8</sup>. 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 Program<sup>9</sup> 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 California<sup>7</sup>) 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 program<sup>2</sup>, 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 set<sup>9</sup> 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 disease<sup>10</sup>. 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 ingested<sup>11</sup>. 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 abuse<sup>12</sup>. California is estimated to spend billions of dollars every year as a result of prescription drug abuse<sup>13</sup>, 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 toilet<sup>14</sup>. 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 health<sup>15</sup>. 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

- <sup>1</sup> “License Type Totals,” *the California State Board of Pharmacy*, July 2, 2019. [https://www.pharmacy.ca.gov/about/license\\_total.shtml](https://www.pharmacy.ca.gov/about/license_total.shtml).
- <sup>2</sup> Subsection (1)(A) of Subdivision (d) of Section 14837 of the Government Code.
- <sup>3</sup> “2017 California Annual Report,” *Mattress Recycling Council California, LLC*, July 1, 2018, pp. 46, 48.
- <sup>4</sup> Snow, Thomas <[Thomas.Snow@dec.ny.gov](mailto:Thomas.Snow@dec.ny.gov)>, “Pharmaceutical Kiosk Pricing Information,” April 23, 2019, office communication.
- <sup>5</sup> “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.
- <sup>6</sup> “Population Projections (Baseline 2016),” *State of California, Department of Finance*, Sacramento, California, January 2018.
- <sup>7</sup> Grimes, William <[William.Grimes@cep.sccgov.org](mailto:William.Grimes@cep.sccgov.org)>, “EPR PharmaSharps – Form 303 and Budget/Cost Information for EPR Program,” September 27, 2018, office communication.
- <sup>8</sup> Lingner, Wanda <[Wlingner@sharpsinc.com](mailto:Wlingner@sharpsinc.com)>, “Sharps Mailback Program Economics,” March 28, 2019, office communication.
- <sup>9</sup> Ross, Rachel, <[RRoss@co.tehama.ca.us](mailto:RRoss@co.tehama.ca.us)>, “Tehama County Pharmaceutical Drug and Medical Waste Sharps Collection Program,” November 05, 2018, office communication.
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- <sup>11</sup> Bond, G. R., Woodward, R. W., & Ho, M., “The growing impact of pediatric pharmaceutical poisoning,” *The Journal of Pediatrics*, 2012, 160(2), 265-270.
- <sup>12</sup> 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.
- <sup>13</sup> 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.
- <sup>14</sup> 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.

- <sup>15</sup> 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>.