

3. STD Form 400 and Notice of Proposed Rulemaking

a. STD Form 400

The form included in this section has been signed by:
Ken DaRosa, Acting Director

b. Attachment A to STD Form 400

c. Updated Informative Digest

d. Notice of Proposed Rulemaking

e. California Regulatory Notice Register Publication

f. STD Form 400 Submitted with NOPA

**State of California
Office of Administrative Law**

In re:
Department of Resources Recycling and
Recovery

Regulatory Action:

Title 14, California Code of Regulations

Adopt sections: 18972.1, 18972.2, 18973,
18973.1, 18973.2, 18973.3,
18973.4, 18973.5, 18973.6,
18974, 18974.1, 18974.2,
18974.3, 18975, 18975.1,
18975.2

Amend sections:

Repeal sections:

**CORRECTED NOTICE OF APPROVAL OF
REGULATORY ACTION**

Government Code Section 11349.3

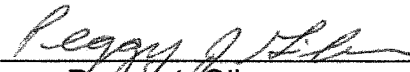
OAL Matter Number: 2020-1119-02

OAL Matter Type: Regular (S)

The Pharmaceutical and Sharps Waste Stewardship Act ("Act") [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)] expands access to proper disposal methods for pharmaceutical and home-generated sharps waste and an education and outreach campaign to promote proper disposal. The Department of Resources Recycling and Recovery in these regulations provides procedures for submittal and approval of Stewardship Plans, as well as reporting requirements and enforcement provisions to implement the Act.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 1/7/2021.

Date: January 7, 2021



Peggy J. Gibson
Senior Attorney

For: Kenneth J. Pogue
Director

Original: Ken DaRosa, Acting Director
Copy: Irina Kaminer

NOTICE PUBLICATION/REGULATIONS SUBMISSION

REGULAR

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2019-1223-02	REGULATORY ACTION NUMBER 2020-1119-02 S	EMERGENCY NUMBER
For use by Office of Administrative Law (OAL) only			
NOTICE		REGULATIONS	
AGENCY WITH RULEMAKING AUTHORITY California Department of Resources Recycling and Recovery (CalRecycle)			AGENCY FILE NUMBER (if any)

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

JAN 07 2021

1:42pm

2020 NOV 19 P 4: 18
OFFICE OF
ADMINISTRATIVE LAW

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER 2020, 01-2	PUBLICATION DATE 1/3/20

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Pharmaceutical and Sharps Waste Stewardship Program	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT 18972, 18972.1, 18972.2, 18973, 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, see Attachment A
	AMEND per agency request
TITLE(S) 14	REPEAL
3. TYPE OF FILING	
<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346) <input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4) <input type="checkbox"/> Emergency (Gov. Code, §11346.1(b)) <input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute. <input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1) <input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h)) <input type="checkbox"/> File & Print <input type="checkbox"/> Other (Specify) _____ <input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100) <input type="checkbox"/> Print Only	
4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1) 01-03-2020 to 02-19-2020, 07-15-2020 to 08-03-2020, and 08-21-2020 to 09-04-2020	
5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100) <input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a)) <input checked="" type="checkbox"/> Effective on filing with Secretary of State <input type="checkbox"/> \$100 Changes Without Regulatory Effect <input type="checkbox"/> Effective other (Specify) _____	
6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY <input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6680) <input type="checkbox"/> Fair Political Practices Commission <input type="checkbox"/> State Fire Marshal <input type="checkbox"/> Other (Specify) _____	
7. CONTACT PERSON Irina Kaminer	TELEPHONE NUMBER 916 341 6396
FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) irina.kaminer@calrecycle.ca.gov

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE 	DATE 11/17/2020
TYPED NAME AND TITLE OF SIGNATORY Ken DaRosa, Acting Director	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JAN 07 2021

Office of Administrative Law

Attachment A to STD Form 400

Continuation of STD Form 400 Section B, 2 – Listing of all section numbers:

18973.6, 18974, 18974.1, 18974.2, 18974.3, 18975, 18975.1, 18975.2

UPDATED INFORMATIVE DIGEST

There have been no changes in applicable laws and effects described in the Notice of Proposed Action. The California Integrated Waste Management Act (CIWMA), Public Resources Code (PRC) section 40000 et. seq., gives the Department of Resources Recycling and Recovery (CalRecycle or Department) authority to provide for the protection of public health, safety, and the environment through waste prevention, waste diversion, and safe waste processing and disposal. PRC section 40502 requires the Department to adopt rules and regulations to implement the CIWMA. Additionally, PRC, section 42031.2 requires the Department to adopt regulations for the implementation of the Pharmaceutical and Sharps Waste Stewardship Program.

The proposed new regulations are intended to clarify the Pharmaceutical and Sharps Waste Stewardship Act [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)].

Minimal changes were made to the regulation provisions stated on the Notice of Proposed Rulemaking, specifically, this regulation covers:

1. Definitions
2. Criteria for determining a covered entity
3. Document submittals: stewardship plan, initial program budget, annual report, and annual budget
4. Document approvals: stewardship plan, initial program budget, annual report, and annual budget
5. Stewardship plan for covered drugs
6. Stewardship plan for home-generated sharps waste
7. Annual report for covered drugs
8. Annual report for home-generated sharps waste
9. Program budgets
10. Record keeping requirements
11. Administrative and Operational Costs and Departmental Administrative Fee
12. Stewardship organization audits of covered entities or authorized collectors
13. Distributor, Wholesaler, Pharmacy, and Retailer Product Verification
14. Criteria to impose an administrative civil penalty
15. Procedure for imposing administrative civil penalties
16. Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting

These regulations incorporated the following documents by reference:

1. The Medicare Benefit Policy Manual, Chapter 15, Section 60.4.1.
2. The Web Content Accessibility Guidelines 2.0 (published in 2008), or a subsequent version, published by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria.

Both of these documents were noticed as available upon request from the agency and are reasonably available from commonly known and specified sources.

A 45-day public comment period for the proposed draft regulations began on January 3, 2020, and written comments were accepted through February 19, 2020. On February 19, 2020, staff held a public hearing on the proposed regulations. After considering comments received during the 45-day comment period and comments made at the public hearing, staff revised the proposed regulations. On July 15, 2020, CalRecycle initiated a 15-day comment period for the proposed changes, which ended on August 3, 2020. After considering comments received during the 15-day comment period, staff revised the proposed regulations. On August 21, 2020, CalRecycle initiated a second 15-day comment period for the proposed changes, which ended on September 4, 2020. After considering comments received during the second 15-day comment period, no further edits to the regulatory text were made. The Final Statement of Reasons describes the specific changes CalRecycle made to the regulatory text at each stage and the purpose and necessity for these changes.

There have been no other changes in the laws related to the proposed action or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Regulatory Action.

On September 30, 2020, Acting Director Ken Da Rosa approved staff's recommendation to adopt the Proposed Regulations, and directed staff to forward them to the Office of Administrative Law for review and publishing. A Notice of Exemption was filed with the State Clearinghouse, as provided under the California Environmental Quality Act.



Department of
Resources Recycling and Recovery

Jared Blumenfeld
Secretary for
Environmental Protection

Scott Smithline
CalRecycle Director

NOTICE OF PROPOSED RULEMAKING

Title 14: Natural Resources

Division 7: Department of Resources Recycling and Recovery

Chapter 11: Product Stewardship

Article 4: Pharmaceutical and Sharps Waste Stewardship Program

Sections: 18972 to 18975.2

PROPOSED REGULATORY ACTION

The California Department of Resources Recycling and Recovery (CalRecycle) proposes to adopt California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972. The proposed regulation is intended to clarify processes for implementing the Pharmaceutical and Sharps Waste Stewardship Act (referred to throughout as the "Act") [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)].

PUBLIC HEARING

A public hearing to receive public comments is scheduled for February 19, 2020. The hearing will be held at the:

Joe Serna Jr., Cal EPA Building
Sierra Hearing Room
1001 I Street, 2nd Floor
Sacramento, CA 95814

The hearing will begin at 1:00 p.m. on February 19, 2020, and will conclude after all testimony is given. Any person may present statements or arguments, orally or in writing, with respect to the proposed action. CalRecycle requests that persons making oral comments also submit a written copy of their testimony at the hearing. The hearing

room is wheelchair accessible. If you have any questions, please contact pharmasharps@calrecycle.ca.gov.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulation. The written comment period for this rulemaking closes on February 17, 2020. CalRecycle will consider only comments received by that time. Comments may be submitted via the contact information below. CalRecycle will also accept written comments during the public hearing described above. Please submit your written comments to:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Fax: (916) 319 – 7147
e-mail: pharmasharps@calrecycle.ca.gov

AUTHORITY AND REFERENCES

Public Resources Code Sections 40401, 42031.2, and 40502 provide authority for this regulation. The purpose of the proposed actions is to implement, interpret, and make specific the law related to pharmaceutical and sharps waste stewardship. The following is a list of references cited in this proposed regulation: sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2, 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2, 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

EXISTING LAWS AND REGULATIONS

The California Integrated Waste Management Act, Public Resources Code Section 40000 et. seq., gives the CalRecycle authority to provide for the protection of public health, safety, and the environment through waste prevention, waste diversion, and safe waste processing and disposal. Public Resources Code Sections 40502 requires CalRecycle to adopt rules and regulations to implement the California Integrated Waste Management Act.

POLICY STATEMENT OVERVIEW AND EFFECT OF PROPOSED RULEMAKING

Pharmaceutical and home-generated sharps waste present significant environmental and public health concerns for California and currently is not managed effectively. As outlined in a 2017 report from the California State Auditor, while greater than 90% of state residents live within a 20-minute drive of a pharmaceutical or home-generated sharps collection site, collection services in rural areas are limited, and approximately

four million Californians do not have reasonable access to disposal sites. Furthermore, information on these collection sites is not readily available to ultimate users. Not all pharmacies, law enforcement agencies, and household-hazardous waste facilities accept pharmaceuticals and/or home-generated sharps; among facilities that do, not all accept Drug Enforcement Administration controlled substances such as prescription opioids or auto-injectors such as Epi-Pens. Currently, options for proper disposal of pharmaceuticals and home-generated sharps waste are complex and confusing, and as a result, these products are often inappropriately disposed in the household garbage, toilets, or sinks.

The Act is meant to address the above problems by expanding access to proper disposal methods for pharmaceutical and home-generated sharps waste and a robust education and outreach campaign to promote proper disposal. The Act places the cost burden of the program on the covered entities of certain pharmaceuticals defined as “covered drugs” and home-generated sharps waste and requires them to manage the home-generated sharps waste collected at local household hazardous waste facilities, which is typically paid for by local governments through general fund, property tax, or ratepayer revenue.

The Act creates a statewide pharmaceutical and home-generated sharps waste stewardship program and requires a program operator, consisting of a covered entity or stewardship organization as defined Section 42030 of the Public Resources Code, to establish and submit to CalRecycle, either individually or collectively through participation in a non-profit stewardship organization, a stewardship plan for covered drugs, home-generated sharps waste, or both.

The proposed regulation is intended to clarify the Act by providing procedures for submittal and approval of Stewardship Plans, as well as reporting requirements and enforcement provisions. More specifically, this regulation includes provisions on the following topics:

1. Definitions
2. Criteria for determining a covered entity
3. Document submittals: stewardship plan, initial program budget, annual report, and annual budget
4. Document approvals: stewardship plan, initial program budget, annual report, and annual budget
5. Stewardship plan for covered drugs
6. Stewardship plan for home-generated sharps waste
7. Annual report for covered drugs
8. Annual report for home-generated sharps waste
9. Program budgets
10. Record keeping requirements
11. Administrative fee to Department of Resources Recycling and Recovery
12. Stewardship organization audits of covered entities or authorized collectors
13. Retailer, wholesaler, distributor product verification

14. Criteria to impose an administrative civil penalty
15. Procedure for imposing administrative civil penalties
16. Procedure for revoking requiring resubmittal, or additional reporting of an approved stewardship plan for failure to meet a material requirement of the statute

The clarification provided in the proposed regulation will assist in the efficient and effective implementation of the Act and, together, the Act and the proposed regulation will lower the cost burden on individuals and local governments for the management of covered drugs and home-generated sharps waste, and will also result in benefits to public health and the environment (discussed in further detail starting on page 7).

Staff held informal public workshops on January 30, 2019 and February 27, 2019 to solicit stakeholder input regarding statutory terms and processes that should be defined and clarified through rulemaking. The input gathered through these workshops, written correspondence, and additional stakeholder meetings was then used to prepare informal draft regulatory text. Staff conducted two additional informal public workshops on May 17, 2019 and June 17, 2019 and held a public comment period to solicit stakeholder feedback on the informal draft regulatory text. Staff then incorporated comments from stakeholders into the proposed regulation.

CONSISTENCY EVALUATION

CalRecycle performed a search of existing state regulations and finds that the proposed regulation is not inconsistent or incompatible with existing state laws or regulations. CalRecycle considered any other possible related regulations and determined that this is the only regulation dealing in this subject area, and CalRecycle is the only agency that can implement this proposed regulation.

PLAIN ENGLISH REQUIREMENTS

CalRecycle staff prepared the proposed regulation pursuant to the standard of clarity provided in Government Code Section 11349 and the plain English requirements of Government Code Sections 11342.580 and 11346.2(a)(1). The proposed regulation is considered non-technical and is written to be easily understood by those parties that will use them.

FORMS INCORPORATED BY REFERENCE

No documents or forms are incorporated by reference in the proposed regulation.

MANDATED BY FEDERAL LAW OR REGULATIONS

Federal law or regulations do not contain comparable requirements.

LOCAL MANDATE

CalRecycle has determined that the proposed regulation does not impose a mandate on local agencies or school districts.

FISCAL IMPACT

COSTS TO ANY LOCAL AGENCY OR SCHOOL DISTRICT REQUIRING REIMBURSEMENT

CalRecycle has determined the proposed regulation does not impact any costs to local agencies or school districts, which must be reimbursed pursuant to Section 6 of Article XIII B of the California Constitution and Part 7 (commencing with Section 17500) of Division 4 of the Government Code. However, at the local government level some current expenditures may be reduced, to the extent that costs related to disposal of home-generated sharps waste may be covered by a stewardship program.

COSTS OR SAVINGS TO ANY STATE AGENCY

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 the Act (including costs incurred prior to 2023) will be reimbursed by covered entities participating in stewardship programs. CalRecycle's costs to oversee implementation of the Act prior to reimbursement will be covered by a loan from CalRecycle's E-Waste program.

NON-DISCRETIONARY COSTS OR SAVINGS

CalRecycle has determined that the proposed regulation does not impose any non-discretionary costs or savings upon local agencies.

COSTS OR SAVINGS IN FEDERAL FUNDING TO THE STATE

CalRecycle has determined that the proposed regulation will not impact federal funding to the state.

HOUSING COSTS

Department staff have determined that the proposed regulation will not have a significant effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

CalRecycle has made an initial determination that the proposed regulation will not have a significant statewide adverse economic impact directly affecting business, including

the ability of California businesses to compete with businesses in other states. While manufacturers of pharmaceuticals and sharps will be responsible for bearing nearly all direct costs of the regulation, these costs represent an insignificant proportion of the profits made on these products.

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.

However, CalRecycle anticipates that the financial impact on a covered entity as a result of the regulation will vary depending on its size. 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.

In 2012, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry association of prescription drug producers, sued the County of Alameda for passing an ordinance establishing a local stewardship program for prescription drugs similar to the one outlined in the Act. PhRMA argued that the Alameda County ordinance violated the Commerce Clause of the U.S. Constitution by affecting the costs for drug producers to operate in California versus other states. The U.S. District Court, Northern District of California sided with Alameda County by ruling that "the Ordinance serves a legitimate public health and safety interest, and that the relatively modest

compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.” PhRMA appealed the ruling up to the U.S. Supreme Court, which declined to hear the case and thus let the District Court ruling stand.

This lawsuit demonstrated that the costs of operating a stewardship program are minimal compared with profits made on prescription drugs. PhRMA estimated that total annual compliance costs in Alameda County would be \$1.2 million, compared with \$965 million in retail pharmaceutical sales. The Department estimates a similar minimal impact for the statewide pharmaceutical program with \$8.9 million in cost versus \$22 billion in revenue. It is reasonable to assume that the impact of the sharps program would be minimal as well.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA

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 Regional Economic Models Inc. (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.

CREATION OF NEW BUSINESSES OR ELIMINATION OF EXISTING BUSINESSES WITHIN CALIFORNIA

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profit organizations, 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.

EXPANSION OF BUSINESSES CURRENTLY DOING BUSINESS WITHIN THE STATE

CalRecycle anticipates a small expansion of waste hauling and disposal businesses within the state.

BENEFITS OF THE REGULATION

CalRecycle has determined that the proposed regulation will result in the following benefits to public health and the environment:

1. Reduction of needle-stick injuries. The regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs by providing consumers with safe and convenient disposal methods for home-generated sharps waste.
2. Reduction of accidental poisonings. The regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications by providing consumers with convenient disposal options and conducting education and outreach campaigns to encourage their use.
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 known gateway to prescription drug abuse and this regulation may make a minor contribution to reducing prescription drug abuse.
4. Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of down the sink or toilet. The regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water by diverting unused covered drugs toward proper disposal methods.

COST IMPACT ON REPRESENTATIVE PERSONS OR BUSINESSES

Although the Act 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 the Act as with any other cost of doing business. 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. Under the most conservative assumption that 100% of program costs are passed on to consumers, the costs per individual in California 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 initially, and \$13.30 annually thereafter.

BUSINESS REPORT

The Act mandates multiple reporting requirements. Program operators are required to annually submit an annual budget and annual report to CalRecycle for approval;

covered entities are required to annually submit product lists to the Board of Pharmacy; and retailers of covered products as well as wholesalers and distributors are required to monitor CalRecycle's website for compliant covered entities and notify CalRecycle if they sell covered products that are not from a compliant covered entity. The proposed regulation does not require additional reports beyond what is laid out in statute, but the regulation does add clarity and specificity to some of these reporting requirements. It is necessary for the health, safety and welfare of the people of the state that the regulations and reporting requirements apply to businesses.

SMALL BUSINESS

Retail pharmacies in California are considered small businesses as most employ fewer than 100 people. Retail pharmacies will be directly impacted by the regulation and will incur costs associated with recordkeeping, occasional reporting to CalRecycle, and distributing sharps containers, which are estimated to cost a combined total of \$100,000 per year split among all the pharmacies, or less than \$50 per pharmacy. 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.

ALTERNATIVES STATEMENT

CalRecycle considered alternatives to the proposed rules and determined that: 1) no alternative would be more effective in carrying out the purpose for which the action is proposed; 2) no alternative would be as effective and less burdensome to affected private persons, while at the same time protecting human health, safety, and the environment, and the integrity of public funds; and 3) no alternative would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. Three specific alternatives are described below.

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 waste 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 Americans with Disabilities Act 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 information technology 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.

ALTERNATIVE 3

The third alternative would be for CalRecycle to not adopt any regulation beyond what is required by subsection (f)(2) of Section 42030 of the Public Resources Code. While this alternative would avoid much of CalRecycle's time and effort spent on the regulatory process, the clarity provided by the regulation is essential to minimize confusion, facilitate effective program implementation, and ensure that ultimate users have adequate access to safe and convenient disposal options for their covered drugs and home-generated sharps waste.

CONTACT PERSON

Inquiries concerning the substance of the proposed action may be directed to:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6676
FAX: (916) 319-7147
e-mail: pharmasharps@calrecycle.ca.gov

Back-up contact person to whom inquiries concerning the proposed administrative action may be directed:

Cynthia Dunn
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery

P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6449
FAX: (916) 319-7495
e-mail: pharmasharps@calrecycle.ca.gov

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATION, AND RULEMAKING FILE

CalRecycle will have the entire rulemaking file, and all information that provides the basis for the proposed regulation, available for inspection and copying throughout the rulemaking process on its internet webpage at <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>. Copies of the rulemaking file may also be obtained by contacting Jason Smyth or Cynthia Dunn using the contact information listed above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulation, the economic and fiscal impact statement, the documents relied upon for the proposed action, and the initial statement of reasons (ISOR).

AVAILABILITY OF CHANGED OR MODIFIED TEXT

CalRecycle may adopt the proposed regulation substantially as described in this notice. If CalRecycle makes modifications, which are sufficiently related to the originally proposed text, it will make the modified text -- with changes clearly indicated -- available to the public for at least 15 days before CalRecycle adopts the regulation as revised. Requests for the modified text should be made to the contact person named above. CalRecycle will transmit any modified text to all persons who testify at the public hearing; all persons who submit written comments at the public hearing; and all persons whose comments are received during the comment period, and all persons who request notification of the availability of such changes. CalRecycle will accept written comments on the modified regulation for 15 days after the date on which they are made available.

FINAL STATEMENT OF REASONS

The Final Statement of Reasons (FSOR) will be made available at the above listed internet webpage or by contacting the people named above.

and could result in minor increases in hunting days and hunter spending on equipment, fuel, food and accommodations.

- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California; Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State’s Environment:

The Commission does not anticipate any impacts on the creation or elimination of jobs, the creation of new business, the elimination of existing businesses, or the expansion of businesses in California. The proposed waterfowl regulations will set the 2020–21 waterfowl hunting season dates and bag limits within the federal Frameworks. Little to minor positive impacts to jobs and/or businesses that provide services to waterfowl hunters may result from the proposed regulations for the 2020–21 waterfowl hunting season.

The most recent U.S. Fish and Wildlife national survey of fishing, hunting, and wildlife-associated recreation for California, estimated that migratory bird hunters contributed about \$169,115,000 to businesses in California during the 2011 migratory bird hunting season. The impacted businesses are generally small businesses employing a few individuals and, like all small businesses, are subject to failure for a variety of causes. Additionally, the long-term intent of the proposed regulations is to sustainably manage waterfowl populations, and consequently, the long-term viability of the same small businesses.

- (c) Cost Impacts on a Representative Private Person or Business:
The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.
- (g) Costs Imposed on Any Local Agency or School District that is Required to be Reimbursed Under Part 7 (commencing with Section 17500) of Division 4, Government Code: None.

- (h) Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

It has been determined that the adoption of these regulations may affect small business. The Commission has drafted the regulations in Plain English pursuant to Government Code Sections 11342.580 and 11346.2(a)(1).

CONSIDERATION OF ALTERNATIVES

The Commission must determine that no reasonable alternative considered by the Commission, or that has otherwise been identified and brought to the attention of the Commission, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

TITLE 14. DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

Title 14: Natural Resources

Division 7: Department of Resources Recycling and Recovery

Chapter 11: Product Stewardship

Article 4: Pharmaceutical and Sharps Waste Stewardship Program

Sections: 18972 to 18975.2

PROPOSED REGULATORY ACTION

The California Department of Resources Recycling and Recovery (CalRecycle) proposes to adopt California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972. The proposed regulation is intended to clarify processes for implementing the Pharmaceutical and Sharps Waste Stewardship Act (referred to throughout as the “Act”) [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)].

PUBLIC HEARING

A public hearing to receive public comments is scheduled for February 19, 2020. The hearing will be held at the:

Joe Serna Jr., Cal EPA Building
Sierra Hearing Room
1001 I Street, 2nd Floor
Sacramento, CA 95814

INFORMATIVE DIGEST/POLICY STATEMENT
OVERVIEW

The hearing will begin at 1:00 p.m. on February 19, 2020, and will conclude after all testimony is given. Any person may present statements or arguments, orally or in writing, with respect to the proposed action. CalRecycle requests that persons making oral comments also submit a written copy of their testimony at the hearing. The hearing room is wheelchair accessible. If you have any questions, please contact pharmasharps@calrecycle.ca.gov.

EXISTING LAWS AND REGULATIONS

The California Integrated Waste Management Act, Public Resources Code Section 40000 et seq., gives the CalRecycle authority to provide for the protection of public health, safety, and the environment through waste prevention, waste diversion, and safe waste processing and disposal. Public Resources Code Sections 40502 requires CalRecycle to adopt rules and regulations to implement the California Integrated Waste Management Act.

POLICY STATEMENT OVERVIEW AND EFFECT OF PROPOSED RULEMAKING

Pharmaceutical and home-generated sharps waste present significant environmental and public health concerns for California and currently is not managed effectively. As outlined in a 2017 report from the California State Auditor, while greater than 90 percent of state residents live within a 20-minute drive of a pharmaceutical or home-generated sharps collection site, collection services in rural areas are limited, and approximately four million Californians do not have reasonable access to disposal sites. Furthermore, information on these collection sites is not readily available to ultimate users. Not all pharmacies, law enforcement agencies, and household-hazardous waste facilities accept pharmaceuticals and/or home-generated sharps; among facilities that do, not all accept Drug Enforcement Administration controlled substances such as prescription opioids or auto-injectors such as Epi-Pens. Currently, options for proper disposal of pharmaceuticals and home-generated sharps waste are complex and confusing, and as a result, these products are often inappropriately disposed in the household garbage, toilets, or sinks.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulation. The written comment period for this rulemaking closes on February 17, 2020. CalRecycle will consider only comments received by that time. Comments may be submitted via the contact information below. CalRecycle will also accept written comments during the public hearing described above. Please submit your written comments to:

Jason Smyth
Materials Management and Local Assistance
Division
California Department of Resources Recycling and
Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Fax: (916) 319-7147
e-mail: pharmasharps@calrecycle.ca.gov

The Act is meant to address the above problems by expanding access to proper disposal methods for pharmaceutical and home-generated sharps waste and a robust education and outreach campaign to promote proper disposal. The Act places the cost burden of the program on the covered entities of certain pharmaceuticals defined as “covered drugs” and home-generated sharps waste and requires them to manage the home-generated sharps waste collected at local household hazardous waste facilities, which is typically paid for by local governments through general fund, property tax, or ratepayer revenue.

AUTHORITY AND REFERENCES

Public Resources Code Sections 40401, 42031.2, and 40502 provide authority for this regulation. The purpose of the proposed actions is to implement, interpret, and make specific the law related to pharmaceutical and sharps waste stewardship. The following is a list of references cited in this proposed regulation: sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2, 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2, 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code.

The Act creates a statewide pharmaceutical and home-generated sharps waste stewardship program and requires a program operator, consisting of a covered entity or stewardship organization as defined Section 42030 of the Public Resources Code, to establish and submit to CalRecycle, either individually or collec-

tively through participation in a non-profit stewardship organization, a stewardship plan for covered drugs, home-generated sharps waste, or both.

The proposed regulation is intended to clarify the Act by providing procedures for submittal and approval of Stewardship Plans, as well as reporting requirements and enforcement provisions. More specifically, this regulation includes provisions on the following topics:

1. Definitions
2. Criteria for determining a covered entity
3. Document submittals: stewardship plan, initial program budget, annual report, and annual budget
4. Document approvals: stewardship plan, initial program budget, annual report, and annual budget
5. Stewardship plan for covered drugs
6. Stewardship plan for home-generated sharps waste
7. Annual report for covered drugs
8. Annual report for home-generated sharps waste
9. Program budgets
10. Record keeping requirements
11. Administrative fee to Department of Resources Recycling and Recovery
12. Stewardship organization audits of covered entities or authorized collectors
13. Retailer, wholesaler, distributor product verification
14. Criteria to impose an administrative civil penalty
15. Procedure for imposing administrative civil penalties
16. Procedure for revoking requiring resubmittal, or additional reporting of an approved stewardship plan for failure to meet a material requirement of the statute

The clarification provided in the proposed regulation will assist in the efficient and effective implementation of the Act and, together, the Act and the proposed regulation will lower the cost burden on individuals and local governments for the management of covered drugs and home-generated sharps waste, and will also result in benefits to public health and the environment (discussed in further detail starting on page 7).

Staff held informal public workshops on January 30, 2019 and February 27, 2019 to solicit stakeholder input regarding statutory terms and processes that should be defined and clarified through rulemaking. The input gathered through these workshops, written correspondence, and additional stakeholder meetings was then used to prepare informal draft regulatory text. Staff conducted two additional informal public workshops on May 17, 2019 and June 17, 2019 and held a public comment period to solicit stakeholder feedback on the infor-

mal draft regulatory text. Staff then incorporated comments from stakeholders into the proposed regulation.

CONSISTENCY EVALUATION

CalRecycle performed a search of existing state regulations and finds that the proposed regulation is not inconsistent or incompatible with existing state laws or regulations. CalRecycle considered any other possible related regulations and determined that this is the only regulation dealing in this subject area, and CalRecycle is the only agency that can implement this proposed regulation.

PLAIN ENGLISH REQUIREMENTS

CalRecycle staff prepared the proposed regulation pursuant to the standard of clarity provided in Government Code Section 11349 and the plain English requirements of Government Code Sections 11342.580 and 11346.2(a)(1). The proposed regulation is considered non-technical and is written to be easily understood by those parties that will use them.

FORMS INCORPORATED BY REFERENCE

No documents or forms are incorporated by reference in the proposed regulation.

MANDATED BY FEDERAL LAW OR REGULATIONS

Federal law or regulations do not contain comparable requirements.

LOCAL MANDATE

CalRecycle has determined that the proposed regulation does not impose a mandate on local agencies or school districts.

FISCAL IMPACT

COSTS TO ANY LOCAL AGENCY OR SCHOOL DISTRICT REQUIRING REIMBURSEMENT

CalRecycle has determined the proposed regulation does not impact any costs to local agencies or school districts, which must be reimbursed pursuant to Section 6 of Article XIII B of the California Constitution and Part 7 (commencing with Section 17500) of Division 4 of the Government Code. However, at the local government level some current expenditures may be reduced, to the extent that costs related to disposal of home-

generated sharps waste may be covered by a stewardship program.

COSTS OR SAVINGS TO ANY STATE AGENCY

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 the Act (including costs incurred prior to 2023) will be reimbursed by covered entities participating in stewardship programs. CalRecycle’s costs to oversee implementation of the Act prior to reimbursement will be covered by a loan from CalRecycle’s E–Waste program.

NON–DISCRETIONARY COSTS OR SAVINGS

CalRecycle has determined that the proposed regulation does not impose any non–discretionary costs or savings upon local agencies.

COSTS OR SAVINGS IN FEDERAL FUNDING TO THE STATE

CalRecycle has determined that the proposed regulation will not impact federal funding to the state.

HOUSING COSTS

Department staff have determined that the proposed regulation will not have a significant effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

CalRecycle has made an initial determination that the proposed regulation will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. While manufacturers of pharmaceuticals and sharps will be responsible for bearing nearly all direct costs of the regulation, these costs represent an insignificant proportion of the profits made on these products.

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.

However, CalRecycle anticipates that the financial impact on a covered entity as a result of the regulation will vary depending on its size. 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.

In 2012, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry association of prescription drug producers, sued the County of Alameda for passing an ordinance establishing a local stewardship program for prescription drugs similar to the one outlined in the Act. PhRMA argued that the Alameda County ordinance violated the Commerce Clause of the U.S. Constitution by affecting the costs for drug producers to operate in California versus other states. The U.S. District Court, Northern District of California sided with Alameda County by ruling that “the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.” PhRMA appealed the ruling up to the U.S. Supreme Court, which declined to hear the case and thus let the District Court ruling stand.

This lawsuit demonstrated that the costs of operating a stewardship program are minimal compared with profits made on prescription drugs. PhRMA estimated that total annual compliance costs in Alameda County would be \$1.2 million, compared with \$965 million in retail pharmaceutical sales. The Department estimates a similar minimal impact for the statewide pharmaceutical program with \$8.9 million in cost versus \$22 billion in revenue. It is reasonable to assume that the impact of the sharps program would be minimal as well.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA

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 Regional Economic Models Inc. (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 percent 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.

CREATION OF NEW BUSINESSES OR ELIMINATION OF EXISTING BUSINESSES WITHIN CALIFORNIA

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profit organizations, 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.

EXPANSION OF BUSINESSES CURRENTLY DOING BUSINESS WITHIN THE STATE

CalRecycle anticipates a small expansion of waste hauling and disposal businesses within the state.

BENEFITS OF THE REGULATION

CalRecycle has determined that the proposed regulation will result in the following benefits to public health and the environment:

1. Reduction of needle-stick injuries. The regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs by providing consumers with safe and convenient disposal methods for home-generated sharps waste.
2. Reduction of accidental poisonings. The regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications by providing consumers with convenient disposal options and conducting education and outreach campaigns to encourage their use.
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 known gateway to prescription drug abuse and this regulation may make a minor contribution to reducing prescription drug abuse.
4. Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of down the sink or toilet. The regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water by diverting unused covered drugs toward proper disposal methods.

COST IMPACT ON REPRESENTATIVE PERSONS OR BUSINESSES

Although the Act 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 the Act as with any other cost of doing business. 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. Under the most conservative assumption that 100 percent of program costs are passed on to consumers, the costs per individual in California 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 initially, and \$13.30 annually thereafter.

BUSINESS REPORT

The Act mandates multiple reporting requirements. Program operators are required to annually submit an annual budget and annual report to CalRecycle for approval; covered entities are required to annually submit product lists to the Board of Pharmacy; and retailers of covered products as well as wholesalers and distributors are required to monitor CalRecycle’s website for compliant covered entities and notify CalRecycle if they sell covered products that are not from a compliant covered entity. The proposed regulation does not require additional reports beyond what is laid out in statute, but the regulation does add clarity and specificity to some of these reporting requirements. It is necessary for the health, safety and welfare of the people of the state that the regulations and reporting requirements apply to businesses.

SMALL BUSINESS

Retail pharmacies in California are considered small businesses as most employ fewer than 100 people. Retail pharmacies will be directly impacted by the regulation and will incur costs associated with recordkeeping, occasional reporting to CalRecycle, and distributing sharps containers, which are estimated to cost a combined total of \$100,000 per year split among all the pharmacies, or less than \$50 per pharmacy. 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.

ALTERNATIVES STATEMENT

CalRecycle considered alternatives to the proposed rules and determined that: 1) no alternative would be more effective in carrying out the purpose for which the action is proposed; 2) no alternative would be as effective and less burdensome to affected private persons, while at the same time protecting human health, safety, and the environment, and the integrity of public funds; and 3) no alternative would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. Three specific alternatives are described below.

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 waste 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 Americans with Disabilities Act 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 information technology 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.

ALTERNATIVE 3

The third alternative would be for CalRecycle to not adopt any regulation beyond what is required by subsection (f)(2) of Section 42030 of the Public Resources Code. While this alternative would avoid much of CalRecycle’s time and effort spent on the regulatory process, the clarity provided by the regulation is essen-

tial to minimize confusion, facilitate effective program implementation, and ensure that ultimate users have adequate access to safe and convenient disposal options for their covered drugs and home-generated sharps waste.

CONTACT PERSON

Inquiries concerning the substance of the proposed action may be directed to:

Jason Smyth
Materials Management and Local Assistance
Division
California Department of Resources Recycling and
Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6676
FAX: (916) 319-7147
e-mail: pharmasharps@calrecycle.ca.gov

Back-up contact person to whom inquiries concerning the proposed administrative action may be directed:

Cynthia Dunn
Materials Management and Local Assistance
Division
California Department of Resources Recycling and
Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6449
FAX: (916) 319-7495
e-mail: pharmasharps@calrecycle.ca.gov

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATION, AND RULEMAKING FILE

CalRecycle will have the entire rulemaking file, and all information that provides the basis for the proposed regulation, available for inspection and copying throughout the rulemaking process on its internet webpage at <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>. Copies of the rulemaking file may also be obtained by contacting Jason Smyth or Cynthia Dunn using the contact information listed above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulation, the economic and fiscal impact statement, the documents relied upon for the proposed action, and the initial statement of reasons (ISOR).

AVAILABILITY OF CHANGED OR MODIFIED TEXT

CalRecycle may adopt the proposed regulation substantially as described in this notice. If CalRecycle makes modifications, which are sufficiently related to the originally proposed text, it will make the modified text — with changes clearly indicated — available to the public for at least 15 days before CalRecycle adopts the regulation as revised. Requests for the modified text should be made to the contact person named above. CalRecycle will transmit any modified text to all persons who testify at the public hearing; all persons who submit written comments at the public hearing; and all persons whose comments are received during the comment period, and all persons who request notification of the availability of such changes. CalRecycle will accept written comments on the modified regulation for 15 days after the date on which they are made available.

FINAL STATEMENT OF REASONS

The Final Statement of Reasons (FSOR) will be made available at the above listed internet webpage or by contacting the people named above.

TITLE 18. DEPARTMENT OF TAX AND FEE ADMINISTRATION

The California Department of Tax and Fee Administration Proposes to Adopt Amendments to Section 1503, *Hospitals and Other Medical Facilities, Institutions and Homes for the Care of Persons, and Section 1591, Medicines and Medical Devices, in Title 18 of the California Code of Regulations*

NOTICE IS HEREBY GIVEN that the California Department of Tax and Fee Administration (CDTFA), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to amend California Code of Regulations, title 18, section (Regulation or Reg.) 1503, *Hospitals and Other Medical Facilities, Institutions and Homes for the Care of Persons, and Regulation 1591, Medicines and Medical Devices*. The proposed amendments to Regulation 1503 clarify that medical service facilities are service providers to their patients and residents, including those insured pursuant to Part A of the Medicare Act. The proposed amendments to Regulation 1503 reformat the second sentence, the third sentence, and both the third and fourth sentences in subdivision (b)(2), as subdivision (b)(2)(A), (B), and (C)1, respectively. The proposed amendments to Regulation 1503 limit reformatted sub-

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2019-122302	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
For use by Office of Administrative Law (OAL) only			
RECEIVED DATE DEC 23 '19		PUBLICATION DATE JAN 03 '19	
Office of Administrative Law NOTICE		REGULATIONS	
AGENCY WITH RULEMAKING AUTHORITY California Department of Resources Recycling and Recovery (CalRecycle)			AGENCY FILE NUMBER (if any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE Pharmaceutical and Sharps Stewardship Program	TITLE(S) 14	FIRST SECTION AFFECTED 18972	2. REQUESTED PUBLICATION DATE 01-03-2020
3. NOTICE TYPE <input checked="" type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON Jason Smyth	TELEPHONE NUMBER 916 341 6676	FAX NUMBER (Optional) 916 319 7147
OAL USE ONLY <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S)	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT
TITLE(S)	AMEND
	REPEAL
3. TYPE OF FILING	
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
	<input type="checkbox"/> File & Print <input type="checkbox"/> Print Only
	<input type="checkbox"/> Other (Specify) _____
4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)	
5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)	
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State <input type="checkbox"/> \$100 Changes Without Regulatory Effect <input type="checkbox"/> Effective other (Specify) _____
6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY	
<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission <input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify) _____	
7. CONTACT PERSON	TELEPHONE NUMBER
	FAX NUMBER (Optional)
	E-MAIL ADDRESS (Optional)

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

For use by Office of Administrative Law (OAL) only

SIGNATURE OF AGENCY HEAD OR DESIGNEE

DATE

TYPED NAME AND TITLE OF SIGNATORY

Elliot Block, Chief Counsel