

9. Public Hearing to Accept Comments on the Proposed Regulation (2/19/2020)

- a. Agenda
- b. Listserv Notice
- c. Transcript



NOTICE OF PUBLIC HEARING

California Code of Regulations

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

Public Hearing on Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Act (SB 212)

A public hearing to receive public comments is scheduled for February 19, 2020 at the following location:

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. and will conclude at 5:00 p.m. or after all testimony is given. Any person may present statements or arguments, orally or in writing, with respect to the proposed action. The hearing room is wheelchair accessible. If you have any questions, please contact pharmasharps@calrecycle.ca.gov.

Agenda

1:00 p.m. – 1:10 p.m.	Introductions and Overview
1:10 p.m. – 4:50 p.m.	Public Provides Comments on Proposed Regulations
4:50 p.m. – 5:00 p.m.	Testimony Concludes

List Archive Message Details

Pharmaceutical and Sharps Waste Stewardship

Message Details

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pharmasharps@calrecycle.ca.gov

Subject

Formal Rulemaking Begins for SB 212 – California’s Pharmaceutical and Sharps Waste Stewardship Program

Message

CalRecycle is required to adopt regulations to implement the Pharmaceutical and Sharps Waste Stewardship Act (Jackson, Senate Bill 212). The Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program clarify statutory requirements including definitions, procedures for the submittal and approval of stewardship plans, annual reports, program budgets, and enforcement provisions for program participants.

Notice of Proposed Rulemaking to implement SB 212 will be published in the California Regulatory Notice Register by the Office of Administrative Law (OAL) (https://oal.ca.gov/publications/notice_register/) on January 3, 2020. This notice begins the formal 45-day comment period of the rulemaking process. The notice, proposed regulatory language, and other relevant rulemaking materials can be found on the Pharmaceutical and Sharps Rulemaking page at: <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>.

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulations. The written comment period for this rulemaking closes on February 17, 2020.

Please submit 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

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1001 I Street, 2nd Floor
Sacramento, CA 95814

Information on the hearing agenda and other related materials, including webcast link for remote participants, can be found on the CalRecycle Public Notice page.

Thank you,

The CalRecycle Pharmaceutical & Sharps Stewardship Team

To unsubscribe from the Medication Disposal: Sharps and Medication listserv, please go to <https://www2.calrecycle.ca.gov/listservs/Unsubscribe/73>.

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Contact: [Public Affairs Office](#) (916) 341-6300

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

IN THE MATTER OF:

PUBLIC HEARING

PROPOSED REGULATIONS FOR THE PHARMACEUTICAL
AND SHARPS WASTE STEWARDSHIP ACT (SB 212)

TRANSCRIPT OF PROCEEDINGS

FEBRUARY 19, 2020

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JOE SERNA JR. - CALEPA BUILDING

SIERRA HEARING ROOM

1001 I STREET, 2ND FLOOR

SACRAMENTO, CALIFORNIA 95814

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APPEARANCES:

CalRecycle Staff

Jason Smyth

Marile Colindres

Cynthia Dunn

Clark Williams

Mark de Bie

Elliot Block

Julie Nguyen

Michael Turgeon

Mary Curry

Joyce Thung

Public Comment

Jason Schmelzer, Shaw Yoder Antwih Schmelzer & Lange, on behalf of the National Stewardship Action Council and the California Product Stewardship Council

James Jack, on behalf of Lil' Drugstore Products and Convenience Valet

John Gay, Pharmaceutical Product Stewardship Work Group

Michael Van Winkle, Executive Director, MED-Project USA

Jennifer Snyder, on behalf of The California Retailers Association, National Association of Chain Drugstores

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1 WEDNESDAY, FEBRUARY 19, 2020

1:00 P.M.

2 ----oOo----

3
4 MR. SMYTH: Okay, folks, the webcast is on
5 so I'm going to go ahead and begin. Good
6 afternoon, everybody. My name's Jason Smyth. I'm
7 the Supervisor of the Pharmaceutical and Sharps
8 Unit. You're at the public hearing for the
9 proposed regulations for SB 212, the Pharmaceutical
10 and Sharps Waste Stewardship Act.

11 I'll be the facilitator today. And before
12 we begin, I'll start with a few housekeeping
13 announcements.

14 First of all, in the unlikely event of a
15 fire alarm we will exit this room through those
16 doors, down the stairs, across the street to Cesar
17 Chavez Park. So, please follow us, so we can get
18 you out there safely.

19 If you're not familiar with the building
20 there's restrooms out these doors to the left, and
21 then another left. There's also a drinking
22 fountain there. And down the stairs there's a
23 cafeteria, if you need coffee or snacks.

24 I'm not sure how long we'll be here today,
25 but if you need to step out and get a coffee or

1 something or take an urgent phone call, please do
2 so out there.

3 This hearing is being recorded. And I
4 want to thank the court reporter in advance for
5 producing a hearing transcript which will be made
6 available as part of the rulemaking file.

7 If you wish to provide a comment today, we
8 ask you to please speak clearly and provide both
9 your name and affiliation, and wait for a
10 microphone to reach you. We'll have microphone
11 runners, as well. And, also, we have the webcast
12 attendees so we want to make sure they can hear you
13 as well.

14 So, with that let's get started. Today
15 marks the final opportunity to provide comments on
16 the proposed regulations for SB 212 as part of the
17 initial 45-day formal comment period. We are here
18 today primarily in a listening mode and to receive
19 your input as part of the formal process. We will
20 not be holding discussions on comments received.

21 I want to acknowledge and thank all of you
22 who have shared feedback already with us, during
23 the course of informal rulemaking, as well as
24 providing comments during the 45-day comment
25 period. We have received a lot of information and

1 helpful suggestions to date.

2 We also anticipate holding a 15-day
3 comment period after we review and evaluate all the
4 comments received to date and determine any
5 necessary edits. We'll keep you informed about our
6 timeline via the rulemaking webpage and the
7 Listserv.

8 If you have comments or suggested edits to
9 the proposed regulatory text, we would like to
10 receive those today so they can be considered.
11 This can be done by providing verbal comments,
12 which will be captured by the court reporter, who
13 will generate a transcript that we will use to
14 respond to the comments.

15 Written comments will also be accepted
16 today by either providing them to us, if you
17 brought hardcopies we have a basket in the back, or
18 if you want to submit them electronically. And if
19 you're attending via webinar, you can send them to
20 pharmasharps@calrecycle.ca.gov before the end of
21 the hearing.

22 Joyce here will be monitoring our inbox so
23 that we can make sure logistical questions get
24 answered and comments regarding the proposed
25 regulations will be added to the rulemaking record.

1 And as a reminder, we do post comments for the
2 public to review on CalRecycle's website.

3 Now, I'd just like to introduce the team
4 whose been working on implementing the law's
5 requirements and developing the proposed
6 regulations. Marile Colindres is one of my staff,
7 as well as Michael Turgeon, Julie Nguygen, Mary
8 Curry. We also have the EPR Manager Cynthia Dunn
9 to my left. Our Branch Chief Clark Williams. Our
10 Deputy of Enforcement Mark de Bie. And our Chief
11 Counsel Elliot Block.

12 With that, I'd like to turn it over to
13 Marile, who will provide a brief overview of where
14 we are in the rulemaking process and walk us
15 through the proposed text. And then, we'll open it
16 up to comments. And I'll just try to keep a queue,
17 moderate, and make sure everybody has a chance to
18 provide comment on the proposed text.

19 MS. COLINDRES: Thank you, Jason. And
20 thank you all for coming out to the CalEPA building
21 this beautiful afternoon. I have had the pleasure
22 of meeting many of you and I'm looking forward to
23 hearing your comments.

24 First, I am going to give a little
25 background about what we have done so far. In

1 January and February 2019, we held our first two
2 public workshops where we solicited stakeholder
3 input and facilitated dialogue on potential
4 regulatory concepts.

5 We then developed informal draft
6 regulatory text and held informal public workshops
7 in May and June to discuss the potential language.
8 We accepted comments on the informal draft text
9 through July 1st.

10 We then incorporated feedback and
11 developed the proposed regulations, which we
12 presented for director approval at the monthly
13 CalRecycle public meeting in October, and which was
14 subsequently approved in November. We also
15 developed other necessary regulatory documents,
16 such as an economic analysis of the proposed
17 regulations, which will be submitted to the
18 Department of Finance for review later this year.

19 In December, we filed with the Office of
20 Administrative Law to begin formal rulemaking, and
21 the notice of proposed rulemaking was published on
22 January the 3rd, 2020, which initiated the 45-day
23 formal comment period that concluded on February
24 17, 2020.

25 Regarding next steps, we will be working

1 on responses to the public comments and revising
2 the regulatory text as needed upon conclusion of
3 today's hearing. We will then hold a 15-day public
4 comment period on the proposed edits.

5 Our intent is for a March through April
6 comment period, but depending on the comments
7 received it may be a bit later. And if further
8 changes to the regulatory text are necessary, we
9 may have subsequent comment periods as well. We
10 will keep you informed.

11 Finally, the regulatory text will be
12 approved by our director at a CalRecycle monthly
13 public meeting before we file the final package
14 with the Office of Administrative Law for their
15 review and approval. We anticipate filing for
16 approval late summer or early fall.

17 Before we move on, Joyce, have we received
18 any logistical questions via email? Thank you.
19 Does anyone in the audience have any logistical
20 questions?

21 Okay, seeing none, now let's go ahead and
22 shift to the proposed regulatory language. We have
23 extra copies in the back if you would like to
24 follow along. And for those of you on the webcast,
25 the proposed regulations are located on our

1 rulemaking webpage.

2 The proposed regulations consist of 17
3 sections and we will be going through the text
4 section by section. When we reach the section that
5 you wish to comment on please raise your hand,
6 state your affiliation, and comment so that it can
7 be accurately captured in this hearing's
8 transcript. If your comment is on a specific
9 requirement, referencing the page and line number
10 will be helpful.

11 So, let's go ahead and begin with the
12 first section, 18972, purpose. This section is
13 intended to summarize the reason for these
14 regulations and identify affected parties in a
15 concise manner. Does anyone have any comments on
16 this first section?

17 Seeing none, we will next move to Section
18 18972.1. This section lists key regulatory
19 definitions that clarify statute.

20 Seeing that there are no comments -- oh,
21 I'm sorry. Thank you very much. We will bring a
22 microphone right to you.

23 MR. SCHMELTER: Ah, thank you. Okay, so
24 this is in our written comments as well. Oh, I
25 should tell you who I am. Jason Schmelzer with

1 Shaw Yoder Antwih Schmelzer & Lange, on behalf of
2 the National Stewardship Action Council and the
3 California Product Stewardship Action -- sorry,
4 California Product Stewardship Council, there's too
5 many councils.

6 Really quick on J: Provides or initiates
7 distribution of sharps waste container. Under 3 it
8 says: Other methods of providing sharps waste
9 container and mail-back materials as approved by
10 the Department, if 1 or 2 are not reasonably
11 feasible.

12 And I would -- so, this is kind of
13 pertaining to the requirement that a sharps
14 container and mail-back materials be provided at
15 the point of sale. And I just want to clarify that
16 in the authorizing statute there is not a
17 feasibility off ramp. There is a legality off
18 ramp. The PRC specifically says that you have to
19 provide the sharps container and mail-back
20 materials at the point of sale to the extent that
21 it's allowable by law.

22 The issue and the reason that that's in
23 the bill is that when the bill was being negotiated
24 sharps manufacturers were concerned that providing
25 the container and the mail-back materials would be

1 considered an illegal inducement under federal law.
2 So, we created an off ramp specifically for that.
3 But there is no feasibility off ramp. It is really
4 just a legality off ramp. If they cannot as a
5 matter of law do that, then there's, you know, an
6 alternative to that.

7 So, we just wanted to make sure. It's a
8 pretty important and that point of sale requirement
9 is really critical to the convenience of the sharps
10 mail-back program.

11 MR. SMYTH: Thank you for the comment.
12 And just to help the audience, it's very helpful if
13 we preface our comments with page 2, line 21 I
14 believe is where you're commenting on. Thank you
15 very much.

16 MS. COLINDRES: Does anyone else have any
17 further comments on the definitions section?

18 Okay, we will move on to Section 18972.2,
19 starting on page 3. This section covers the
20 criteria for determining a covered entity.

21 MR. JACK: Good afternoon. My name is
22 James Jack and I am here on behalf of Lil'
23 Drugstore Products and Convenience Valet. And I
24 missed the few moments of the hearing and I just
25 wanted to clarify, are you accepting questions or

1 is it strictly comments? Comments only?

2 MR. SMYTH: Comments only.

3 MR. JACK: Okay, thank you. So, and this
4 is also pursuant to the written comments that we
5 had submitted. Both of our clients I think share
6 concerns around what types of scenarios would
7 potentially trigger the covered entity
8 responsibility shifting from the manufacturer to
9 one of the other entities that are referenced, and
10 this is on page 3, starting on line 15 through 18.
11 We know that, obviously, Senate Bill 212 created
12 kind of a cascading list of other potential
13 responsible parties if a manufacturer is not
14 identified. And we would just encourage the staff
15 to articulate clearly, potentially in the next set
16 of revisions to the proposed regulation what
17 efforts CalRecycle would have to take to identify a
18 manufacturer for purposes of the program before
19 that responsibility could be assigned elsewhere.
20 Thank you.

21 MR. SCHMELZER: Jason Schmelzer again, on
22 behalf of CPSC and NSCA. We actually have a very
23 similar point. There's really no indication in the
24 regulations about when you move up or down the
25 list. If there's an approved plan and suddenly

1 it's disapproved, what's the notice to the
2 distributors, you know, retailers, et cetera down
3 the list? Is there going to be any sort of
4 notification process? What are the timelines for
5 them coming into compliance? It's really just
6 unclear at this point how you move up or down that
7 list. So, we would echo his comments, frankly.
8 Thanks.

9 MS. COLINDRES: Thank you very much,
10 gentlemen, for those comments.

11 Section 18973 is our next area we will be
12 discussing. The process to submit documents to the
13 department.

14 Seeing that there are no comments for that
15 particular section -- oh, I'm sorry about that.

16 MR. GAY: Sorry about that, I didn't know
17 if you were going to point 1 point -- I saw that
18 point 1 was next.

19 So, my name is John Gay. I'm with the
20 Pharmaceutical Product Stewardship Work Group,
21 known as PPSWG. We are a membership organization
22 with over 400 members and affiliate companies
23 across the broad spectrum of pharmaceutical
24 products and sharps manufacturers. And PPSWG has
25 established MED-Project USA, which also will be

1 testifying, to develop, implement, and operate
2 stewardship programs for unwanted drugs and sharps.

3 The item I want to focus on here is we're
4 concerned that in 18973.1 the proposed regulations
5 -- and I'll give you the -- the page number is 17,
6 the line is 13.

7 The proposed regulations' proposal could
8 require the submission of updated, verified, or
9 reverified lists of covered products in annual
10 reports, which is contrary to what is required by
11 SB 212.

12 Section 42031(a)(2) of SB 212 requires
13 that covered entities or a stewardship organization
14 update and submit a list of covered products to the
15 Board of Pharmacy on or before January 15th, each
16 calendar year. The bill does not impose any new
17 obligations on program operators during the annual
18 reporting process. I.e., there's no obligation to
19 prepare new, updated or reverified lists of covered
20 products during that roughly two and a half month
21 period between January 15th for the pharmacy
22 submission, and the March 31st annual reporting
23 deadline.

24 Rather, the legislative intent was simply
25 to and only to require that the same covered

1 products list be resubmitted to the Board of
2 Pharmacy on January 15th -- that was submitted on
3 January 15th be included in the annual report
4 submitted to CalRecycle on March 31st.

5 However, the section I noted of the
6 proposed regulation states, without further
7 elaboration, that the annual report submitted to
8 CalRecycle for a covered drug stewardship plan must
9 include, quote "A list of covered products",
10 unquote.

11 And the section -- similarly, and I don't
12 know if you want to raise it now, but there's
13 another, a similar issue in the sharps program.
14 Did you want to hear it now or do you want to wait
15 for that? Nodding yes for now or --

16 MS. COLINDRES: Wait for that.

17 MR. GAY: Okay, wait for that.

18 MR. SMYTH: So, we're trying to receive
19 comments on 18973, the document submittals portion.

20 MR. GAY: Yes.

21 MR. SMYTH: That's separate from the
22 annual report section --

23 MR. GAY: Oh, I'm sorry.

24 MR. SMYTH: -- which is coming later.

25 MS. COLINDRES: Does anyone have any

1 comments on Section 18973, the process to submit
2 documents to the department?

3 Seeing none, we will move on to Section
4 18973.1. This section outlines the document review
5 and approval process.

6 Our next section that we will be covering
7 starts on page 5. This section covers the required
8 components of a stewardship plan for covered drugs.

9 MR. JACK: Hello again, James Jack again,
10 on behalf of Lil' Drugstore Products and
11 Convenience Valet.

12 So, the two companies that we're here
13 today representing are both members of PPSWG and
14 various other jurisdictions where take-back
15 programs have been created. And one suggestion
16 that we would like to make to the department
17 regarding this section is inherently there is a
18 natural desire within stewardship organizations to
19 spread the cost of the program across as many
20 entities as possible to reduce the overall burden
21 to any particular entity with regard to the cost of
22 administering the program.

23 However, a situation will likely exist
24 where members of the pharmaceutical supply chain,
25 who are not the covered entities could potentially

1 be looked to as -- for financial or program support
2 through a stewardship organization, even if they
3 are not defined under the regulation as the covered
4 entity for that covered drug.

5 And so, the clarification that we would
6 request that I think would create a lot of
7 uncertainty for smaller companies, like the two
8 that we represent, is that participation in the
9 stewardship group shall not be required unless you
10 are a covered entity for a covered drug under the
11 program. Thank you.

12 MR. SCHMELZER: Hey, Jason Schmelzer for
13 CPSC and NSAC, again. We would do page 6, line 21
14 and 22, where it's talking about creating a
15 description for the process in which good faith
16 negotiations with potential authorized collectors
17 is conducted.

18 We would ask that there would be a
19 separate process described for authorized
20 collectors who request to join the program
21 specifically under 42032.2(b)(3) of the PRC.
22 That's the provision that says, you know, once a
23 plan has been approved and once the minimum
24 convenience standard has been met that any
25 authorized collector, any valid authorized

1 collector can request to join the Med Program and
2 needs to be basically brought in within 90 days.

3 This is an extremely important provision
4 in the bill. This was kind of the balancer on
5 meeting the convenience standard. There's a kind
6 of a numerical convenience standard and this was
7 the stop gap to make sure that any holes were
8 filled. So, we think that's a very important
9 process and we want to see that measured very
10 specifically. Because to us, that's part of the
11 convenience standards is, you know, those
12 requesters joining and how they're dealt with and
13 processed.

14 And we would kind of extend that further
15 to say if they're rejected for any reason, once
16 they've requested to join, we think the stewardship
17 organization should have to provide an explanation
18 as to why they were rejected.

19 MR. VAN WINKLE: Good afternoon. My name
20 is Mike Van Winkle. I'm the Executive Director of
21 MED-Project USA. MED-Project USA was established
22 by the Pharmaceutical Product Stewardship Work
23 Group to develop, implement and operate stewardship
24 programs for unwanted pharmaceutical products and
25 sharps from households on behalf of the PPSWG

1 members and producers.

2 MED-Project does have substantial on-the-
3 ground experience across a number of jurisdictions
4 in the country, including local jurisdictions here
5 in California.

6 We appreciate the opportunity to submit
7 this testimony. And I do have one issue on this
8 section I'd like to bring forward. And that while
9 we've provided substantial written comments, one of
10 the things that we'd point out in this section is
11 that CalRecycle should revise the regulations to
12 recognize the appropriate program operator roles as
13 contemplated in the SB 212.

14 To basically operate successful and
15 compliant stewardship programs, program operators
16 can support collection site and program vendor
17 compliance, but they cannot ensure these
18 independent entities comply with their independent
19 legal obligations.

20 You know, while program operators can
21 describe processes to address certain critical
22 collection site, or certain provider policy or
23 procedure deviations, only government agencies can
24 conclusively determine that collection services or
25 service providers are in noncompliance.

1 MR. SCHMELZER: Hey, thank you. I'm going
2 to try to find the line and the page. Jason
3 Schmelzer on behalf of CPSC and NSAC, again. Page
4 8, line 23 to 26, on ordinance repeals.

5 So, the coverage for the entire program,
6 whether it's meds or sharps, obviously the program
7 does not apply and program operators, and
8 stewardship organizations don't have to cover a
9 county where there's an existing ordinance. But
10 part of what we've set up in the bill is a process
11 whereby a stewardship organization or a program
12 operator can negotiate with a county with an
13 ordinance to get them to repeal their ordinance and
14 come into the statewide program, which I think is
15 important.

16 But to the extent that that happens I
17 think, and to the extent that you can, the
18 regulations need to help control that process. Let
19 me give you an example. Say there's a county with
20 an existing local ordinance that has requirements
21 that are higher than what's in the legislation, so
22 they negotiate to repeal their ordinance and come
23 into the statewide program, but there's conditions
24 for that county. Yes, we will join the statewide
25 program, but you have to provide us with this level

1 of service for us to repeal the ordinance.

2 Well, the ordinance repeal is going to be
3 permanent. So, to the extent that CalRecycle can,
4 we'd like to examine ways were that kind of deal,
5 that negotiation, the conditions for leaving the
6 local program and joining the statewide program are
7 preserved. Program operators will change.

8 Stewardship organizations may change. If a county
9 negotiates with one program operator, but then they
10 go away and a new operator comes in to run the
11 program, are those negotiations going to carry
12 forward? How does that process work? Because it
13 won't happen if counties don't have certainty. And
14 there obviously is some value to bringing everybody
15 into one program as far as efficiency, et cetera.

16 So, to the extent that the department can
17 kind of help control that situation, we think it
18 would be helpful.

19 MS. COLINDRES: Thank you for your
20 comments. We will now -- oh, one more.

21 MS. SNYDER: I'm Jennifer Snyder, on
22 behalf of the California Retailers Association,
23 National Association of Chain Drugstores.

24 I just want to make a note, this is
25 relative to Section 18973.2, paragraph G, I think

1 it's 8. I don't know the exact line or page number
2 because I just put that down. So, it looks like
3 it's line 9, I think.

4 So, this has to do with collection site
5 maintenance. And organizations I represent have
6 turned in some written comments, but I just wanted
7 to note this one in particular. For them, I think
8 also in our discussions with the Pharmacist
9 Association and the Independent Pharmacies, there's
10 a lot of concern about collection site maintenance
11 and making sure that program operators that work
12 with pharmacies effectively help them with
13 collection site maintenance. And many of them have
14 a lot of concerns about that their collection sites
15 are not properly maintained. And they don't really
16 have accessibility or know who to report that to,
17 who to call.

18 So, we would look for stronger language in
19 paragraph 8 with respect to keeping program
20 operators accountable for, if we're going to have
21 collection receptacles that they're properly
22 maintained.

23 MR. SMYTH: And to clarify for the hearing
24 transcript, I believe you're commenting on page 8,
25 lines 6 through 8.

1 MS. COLINDRES: Okay, we will now move on
2 to Section 18973.3, starting on page 9. This
3 section covers the required components of a
4 stewardship plan for home-generated sharps waste.

5 MR. SCHMELZER: Hey, Jason Schmelzer for
6 CPSC and NSAC. Again, we just want to kind of
7 double down on the comment that we made earlier
8 about how important the issue of providing at the
9 point of sale, providing or initiating distribution
10 of the sharps mail-back container at the point of
11 sale is -- the law is drafted very tight, drafted
12 very tightly to make sure that this occurs. So,
13 it's just paramount importance.

14 Frankly, I think from a negotiating
15 perspective, the folks that were for the program in
16 the first place, we weren't really comfortable with
17 the mail-back program, and that convenience factor
18 again is really central.

19 One thing that's not anticipated by the
20 regulations, but that we think would be helpful,
21 when we were talking about the bill with the sharps
22 manufacturers they said, hey, we may want to do,
23 you know, a container for three months' worth of
24 sharps, you know, and not at every point of sale.
25 Maybe we know somebody gets 30 a month and we want

1 to give them a container for a hundred sharps. We
2 should be able to do that. How can you do that if
3 you're supposed to give them something at the point
4 of sale every time?

5 So, maybe the regulations should
6 anticipate the program providing larger containers
7 for multiple months or multiple purchases, and how
8 they would kind of work that out.

9 We would just say one thing, which is, you
10 know, the containers need to be of suitable size
11 and weight when they're full for consumers to
12 actually be able to take them and carry them to an
13 appropriate drop off facility, or take them to be
14 mailed, or what have you, so.

15 MS. COLINDRES: Seeing no other comments
16 for Section 18973.3, we will move on to the next
17 section, 18973.4. This section covers the required
18 components of annual report for covered drugs.

19 MR. GAY: This is definitely the right
20 time for me to talk, right. Thank you. And thank
21 you for your patience. So, I won't go back all the
22 way but, let me see, what we're talking about is
23 page 17, line 13.

24 MS. DUNN: Sorry, can you please state
25 your name and affiliation again? Thanks.

1 MR. GAY: I will start over again. My
2 name is John Gay. I'm Vice President for
3 Legislative and Regulatory Affairs with PPSWG, the
4 Pharmaceutical Products Stewardship Working Group.
5 We appreciate the opportunity to give comments
6 here. We have written comments as well.

7 I will raise two points. First, we would
8 like to support the comments submitted by MED-
9 Project. And, secondly, to talk about the issue
10 that I started to talk about earlier, which occurs
11 on page 17, line 13.

12 The concern is that the provisions in the
13 proposed regulations could require the submission
14 of updated, verified, or reverified lists of
15 covered products in annual reports, contrary to
16 what is required by SB 212. SB 212 requires that
17 covered entities or a stewardship organization
18 update and submit a list of covered products to the
19 Board of Pharmacy on or before January 15th of each
20 calendar year.

21 SB 212 does not impose any new obligations
22 on program operators during the annual reporting
23 process, i.e. there's no obligation to prepare new,
24 updated or reverified lists of covered products
25 during the roughly two and a half month period

1 between the January 15th Board of Pharmacy
2 submission and the March 31st annual operating --
3 or annual reporting deadline.

4 Rather, the legislative intent was simply
5 and only to require that the same covered products
6 list submitted to the Board of Pharmacy on January
7 15th be included in the annual report submitted to
8 CalRecycle on March 31st.

9 However, the provision I mentioned,
10 18973.4(j)(2) of the proposed regulation states,
11 without further elaboration, that the annual report
12 submitted to CalRecycle for covered drug
13 stewardship plan must include, quote, "a list of
14 covered products", unquote.

15 As drafted, this language in the proposed
16 regulations could be construed as imposing
17 additional obligations on program operators to
18 undertake another exercise in preparing a different
19 update or reverified list of covered products
20 included in the March 31st annual report
21 submissions.

22 Accordingly, we suggest that this
23 provision of the proposed regulation should be
24 revised to be consistent with SB 212.

25 I have a similar one for the later -- for

1 the covered sharps, but would you like me to wait
2 for that one?

3 MR. SMYTH: Yeah, we're aiming for a
4 chronological sequence of comments so, thank you.

5 MR. WILLIAMS: And, John thanks for your
6 patience and indulgence here with us in repeating
7 your name and affiliation in your comments. It
8 does help get an accurate transcript to make sure
9 we follow up. Thank you.

10 MS. COLINDRES: We will now move on to the
11 next section, 18973.5. This section covers the
12 required components of an annual report for home-
13 generated sharps waste.

14 MR. GAY: Should I start the whole thing
15 again?

16 MR. SMYTH: You don't have to do the whole
17 thing, but please identify yourself and the
18 comments in this section.

19 MR. GAY: Okay. I'm John Gay, Vice
20 President of Legislative and Regulatory Affairs for
21 PPSWG, the Pharmaceutical Products Stewardship
22 Workgroup.

23 The issue I'd like to raise this time is
24 on page 20, line 5, Section 18973.5(k). Similar to
25 what I mentioned earlier, this provision states

1 that: The annual reports for a home-generated
2 sharps waste stewardship plan must include, quote,
3 "Updated", unquote -- "Updated list of covered
4 products", unquote.

5 So, as drafted, this language in the
6 proposed regulations could be construed as imposing
7 additional obligations on program operators to
8 undertake another exercise in preparing a
9 different, updated, and/or reverified list of
10 covered products to include the March -- products
11 to include in the March 31st annual report
12 submission.

13 Accordingly, we suggest that Section
14 18973.5(k) of the proposed regulations should be
15 revised to be consistent with SB 212.

16 MR. SCHMELZER: Jason Schmelzer, CPSC,
17 NSAC. I guess in response, if I can, it seems like
18 42033.2(b) says that an annual report submitted
19 shall include at a minimum all of the following.
20 It seems like you guys have pretty broad authority
21 to include other things that you think are
22 important under that piece of language. So, I
23 would point that out.

24 And then, second, page 20, line 13 on the
25 local agency requests, again this was another

1 really important piece with respect to the sharps
2 program. There was some discomfort with the mail-
3 back structure as opposed to a kiosk-based system.
4 So, the point of this is to catch any sharps that
5 fall through the cracks so to speak and end up at
6 local government facilities.

7 So, in the annual report what we'd like to
8 see is the language expanded, which we think you
9 can do, to say that the annual report should
10 include a specific list of the local jurisdictions
11 that have requested either pickup or reimbursement
12 under the law, the date of the request, the date of
13 the response, and the ultimate disposition, what
14 happened.

15 And if, for whatever reason, the request
16 was rejected there should be an explanation about
17 why the request was rejected. So, we would ask
18 that to be included.

19 MR. VAN WINKLE: Mike Van Winkle, again,
20 MED-Project -- MED-Project USA Executive Director.

21 So, in this section, 18973, it's a broad
22 comment for this and it probably does apply also
23 back to the 18973.4. That the pharmaceutical and
24 sharps waste program was established by SB 212 is
25 not publicly funded, like other extended producer

1 responsibility programs established by the
2 Legislature in California.

3 And under SB 212, this stewardship program
4 is wholly funded by the covered entities. This
5 distinction was relevant to the Legislature and
6 should be honored in the proposed regulations. The
7 amount of supplemental information and level of
8 detailed oversight sought by CalRecycle in the
9 annual reporting, and then also, then, in the
10 following budget section does not account for this
11 private funding scheme and this appears
12 inconsistent with SB 212.

13 So, we've got a number of comments on
14 this, so I'd refer you to our written comments that
15 we think should be revised for this distinction, in
16 line with the level of detail intended by the
17 Legislature.

18 MS. COLINDRES: Thank you for your
19 comment. We will now move on to Section 18973.6,
20 starting on page 21. This section covers the
21 required components of an initial and annual
22 stewardship program budget.

23 MR. SCHMELZER: Jason Schmelzer, CPSC,
24 NSAC. I guess I can ask this question in the
25 context of this section, but it actually kind of

1 applies across the board to the regulations. On
2 page 21, line 2 there's this reference to, you
3 know, the first five calendar years of operation.
4 You know, provide the budget for the first five
5 years of operation.

6 It seems like throughout the regulations
7 we're leaning towards a five-year plan, but it
8 never says that. So, I guess I would just suggest
9 if what CalRecycle is anticipating is kind of a
10 long-term plan that's implemented over time, and
11 there's a long-term budget, and things like that
12 that maybe that just be called out very
13 specifically in the regulations. Hey, here's going
14 to be the duration of the plan. It would just give
15 everybody more certainty as to what they're looking
16 at. Because looking at the regulations I can't
17 really tell if they could propose a three-year plan
18 that has like a five-year funding structure, it's
19 just a little bit unclear. So, I'd just make a
20 general comment about that.

21 MS. COLINDRES: Thank you for your
22 comment. Seeing no further comments on the annual
23 and initial stewardship program budget, we will
24 move on to Section 18974, starting on page 22.
25 This section lists various recordkeeping

1 requirements.

2 Seeing that there are no comments on this
3 section, we will move on to 18974.1, starting on
4 page 23. This section covers the administrative
5 fee paid to the department.

6 Excuse me. With no comments on that
7 section, we will move on to Section 18974.2. This
8 section covers stewardship organization audits of
9 covered entities or authorized collectors.

10 With no comments on that section, we can
11 move on to Section 18974.3. This section covers
12 product verification requirements of retailers,
13 wholesalers, and distributors.

14 And we will move on to the next section,
15 18975, starting on page 24. This section lists the
16 criteria for imposing an administrative civil
17 penalty.

18 MR. SCHMELZER: Hey, Jason Schmelzer,
19 CPSC, NSAC. I took my glasses off. Page 24, line
20 7. So, I guess this is more of a general comment
21 than what's in the regulations. The statute's
22 pretty limited as far as the application of civil
23 penalties. It's really only as you've described it
24 in that paragraph.

25 So, I think we would make a comment about

1 your general enforcement posture, which is there's
2 a lot of other very important aspects of this
3 program that can't be penalized through civil
4 penalties. Rejecting local government requests for
5 pickup would not be punishable under a civil
6 penalty. That's not -- that doesn't meet the test
7 under the statute or the regulations.

8 Failing to provide the sharps container at
9 the point of sale does not count for civil
10 penalties.

11 Which means, really, your only recourse if
12 there are problems, which I actually don't expect
13 there will be, respectfully I don't think there are
14 going to be problems. But if there is, really your
15 only recourse is an aggressive policy related to
16 repeal, suspension, revocation, whatever you want
17 to call it of the plan then you can impose civil
18 penalties.

19 So, we would just suggest that if for
20 whatever reason there are problems such as that on
21 key provisions of the requirements under the law,
22 that CalRecycle take a very aggressive enforcement
23 posture. Because there have been other programs in
24 the past that have floundered because of difficulty
25 with enforcement and this one, obviously, that we

1 really want to work very well.

2 So, being as that you have limited tools,
3 we would say use them aggressively to the extent
4 that you have to.

5 MS. COLINDRES: Thank you for your
6 comment. We will move on to the next section,
7 18975.1, starting on page 25. This section
8 outlines the procedure for imposing an
9 administrative civil penalty.

10 Seeing no raised hands, we will move on to
11 Section 18975.2. This section outlines the
12 procedure for revoking a stewardship plan,
13 requiring plan resubmittal, or requiring additional
14 reporting for failure to meet a material
15 requirement of the statute.

16 MR. SCHMELZER: Jason Schmelzer, CPSC,
17 NSAC. Following up on my prior comment, this is
18 where it might be a good idea to telegraph both to
19 the program operators and, you know, people who are
20 going to be using the program if there are certain
21 things that will automatically trigger a revocation
22 process. Again, doing some of those big ticket, or
23 failing to do some of those big ticket items in the
24 bill, maybe if -- maybe it doesn't belong here.
25 I'm not sure, I'm not a regulator. But maybe the

1 regulations could anticipate certain offenses we're
2 going to move straight to revocation, we're not
3 messing around. Very strict enforcement posture.
4 Thank you.

5 MS. COLINDRES: Thank you for your
6 comment. Are there any other comments on this
7 section?

8 MR. SMYTH: Okay, Joyce, did we get any
9 additional logistical questions online?

10 JOYCE: No, we did not receive any
11 comments or comment letters during this hearing.

12 MR. SMYTH: Okay, thank you, Joyce. So,
13 before we conclude are there any other general
14 comments that didn't fit the sequence that we just
15 went through?

16 MR. VAN WINKLE: Mike Van Winkle,
17 Executive Director of MED-Project USA, and thanks
18 for the opportunity to comment.

19 So, as I think we brought up before, and
20 certainly in our written comments, and many
21 detailed discussions, SB 212 is a very detailed and
22 prescriptive statute. And the proposed regulations
23 build on this already detailed framework and in
24 many ways adding new requirements and in other ways
25 creating some inconsistent obligations or

1 ambiguities where conflicting readings are
2 potentially possible. And a full list of these
3 additions, and inconsistencies, ambiguities are
4 included in our written comments.

5 And our request is that these should be
6 eliminated to preserve the language and intent of
7 SB 212 to maintain its flexibility which in turn
8 will promote a successful program operation. And
9 thank you, again, for MED-Project's ability to
10 provide comments.

11 MR. SMYTH: Going once. Going twice.
12 Okay, thank you all for your comments today on the
13 regulations. Once again, please direct any
14 questions to pharmasharps@calrecycle.ca.gov, and
15 subscribe to our Listserv for updates on the
16 rulemaking process.

17 This concludes our formal hearing today.
18 So, thanks everybody and have a great afternoon.

19 (Off the record at 1:44 p.m.)

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REPORTER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were reported by me, a certified electronic court reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 3rd day of March, 2020.



Eduwiges Lastra
CER-915

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I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 3rd day of March, 2020.



Barbara Little
Certified Transcriber
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