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Subject: **Second Draft Proposed Regulations (July 2020)**
Pharmaceutical and Sharps Waste Stewardship Program

Dear Mr. Smyth,

We, the undersigned organizations, would like to thank you for the opportunity to submit comments on the second draft of proposed regulations to implement the Pharmaceutical and Sharps Waste Stewardship Program established by SB 212 (2018 - Jackson, Ting, and Gray). The work you are doing to implement this program for the people of California is vitally important, and we hope our comments provide additional perspective as you complete this task. We have provided several comments below on specific portions of the regulations that have been amended in the most recent draft.

Proposed Regulations are Inconsistent with Authorizing Statute

The core of the sharps program is the requirement that a sharps waste container and mail-back materials are either provided to the ultimate user at the point of sale, or the provision of those materials is initiated at the point of sale. This requirement functions as the convenience standard for this program and is therefore quite important to proper operation. The language in PRC 42032.2(d)(1)(F)(i) is very clear:

"The program provides or initiates distribution of a sharps waste container and mail-back materials at the point-of-sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected period of time."

For purposes of establishing a foundational fact for the comment we are about to make, we'd stress that the authorizing statute simply does not allow a program operator any flexibility in the requirement to provide or initiate distribution of a sharps container and mail-back materials at the point of sale unless providing or initiating distribution at the point of sale is specifically prohibited by law.

The problem with both the first and second draft of proposed regulations is that they allow a program operator an offramp from the statutory requirement to provide the sharps container and mail-back materials at the point of sale for a reason that is simply not allowed by the law – feasibility.

Section 18972.1(a)(11) creates a definition for “Provides or initiates the distribution of a sharps waste container” and provides three possible meanings for this phrase. Two of them – 18972.1(a)(11)(A) and (B) are consistent with the authorizing statute, but (C) is not. As we note above, (C) states that a program operator can utilize “other methods” if the options in (A) or (B) are not allowed by law or “is not reasonably feasible”. The department simply does not have authority under the authorizing statute to make the allowance for “other methods” if feasibility is the only perceived barrier to providing a sharps container and mail-back materials at the point of sale under (A) or initiating the distribution of those items at the point of sale under (B). This should be struck from the definition.

Although we believe the legal reality described above is unquestionably accurate, we’d also like to make a more general argument in favor of striking the allowance of “other methods” based on feasibility. SB 212 was largely a negotiated compromise – especially the sharps portion of the bill. The sharps industry insisted on a mail-back only program. Stakeholders, to ensure the success of this industry-devised mail-back method, insisted on some very important provisions. Those are:

- That the mail-back container and materials be provided at the point of sale. This is vitally important to ensuring convenience for consumers. We know through experience all over the world that convenience is the most important factor in determining the success of producer responsibility programs and so this was an extremely important requirement.
- That program operators be responsible for either reimbursing local governments for sharps disposal of sharps in the waste stream or come pick them up and dispose of them.

Combined, these two provisions ensure convenience for the ultimate user and create a significant incentive for the producer to design and implement an effective program. They are foundational to the effective operation of the mail-back only program. We do not believe that the regulations should even consider the possibility of a stewardship plan for sharps that does either provide or initiate the delivery of the sharps container and mail-back materials at the point of sale unless there is a demonstrable legal concern. To do so would be inconsistent with legislative intent.

We strongly encourage the department to strike the words “or is not reasonably feasible” from lines 5 and 6 of page 3 of the second draft of proposed regulations because they are inconsistent with the authorizing statute and could significantly weaken the program.

Enforcement of Implementation Timeline and Programmatic Requirements

Our major concern in this area is that the department, to the degree possible, avoids a situation where the process of submitting, reviewing, and approving stewardship plans doesn’t drag on in ways that jeopardize program efficacy, such as multiple resubmittals of the draft plan or future amendments to the plan. We commented on our past letter about the process for determining plan completeness, as well as the process for approving/disapproving plans. While the second draft of proposed regulations don’t necessarily adopt our prior suggestions, we do believe that the statute and regulations provide the department enough authority to enforce the law.

PRC 42032(a)(1) requires a program operator to submit a complete stewardship plan that meets the requirements of the law within six months of the regulations being approved. PRC 42032(g) requires a program operator to fully implement their stewardship plan within 270 days of the department’s

approval. PRC 42035.2 gives the department authority to impose a civil penalty to a covered entity, program operator, or stewardship organization that provides, sells, or offers for sale a covered product that isn't covered by a stewardship plan. We believe the regulations, in Sections 18975, 18975.1, and 18975.2, also provide the department with the tools necessary to ensure that this program is implemented in a timely and effective manner.

We strongly encourage the department to utilize this enforcement and penalty authority if program operators do not meet implementation timelines and standards. The covered entities required to perform under the law have years of experience implementing local ordinances and will have had nearly three years of ramp-up time between the passage of SB 212 and the deadline to implement the program. There is simply no excuse for a program operator to be unprepared to meet their responsibility under the law.

Similarly, we hope the department will utilize its authority in Section 18975.2 to enforce key aspects of the program. Subsection (a) requires the department to revoke a previously approved stewardship plan if the department finds that a material requirement of the article is not being met by a program operator.

Education & Outreach Program

Product stewardship programs cannot work if they are difficult to understand and navigate. The education and outreach portion of the stewardship plans needs to be robust, consistent, and accessible by all Californians. We strongly support the changes to the education and outreach portions of the regulations (Section 18973.2(j) for medicines and 18973.3(i) for sharps) because they significantly strengthen the regulations and provide clear direction to program operators.

The second draft proposed regulations require program operators to coordinate closely with other program operators or stewardship organizations on their efforts to promote awareness and participation in their stewardship programs, develop educational signage and materials in multiple languages depending on local need, develop internet websites and mobile platforms to provide vital information, establish a toll-free telephone number that provides service for the hearing- and speech-impaired and is also answered by a human representative, and metrics to evaluate and recalibrate efforts as needed. All of these components are necessary for an effective education and outreach program and we support their inclusion in the regulations.

While we understand that the plan development, submission, and approval process will ultimately determine what is in the actual education and outreach programs, we believe the regulations provide a strong foundation for success. We urge the department to be vigilant in terms of this portion of the product stewardship plan – if program operators don't get the education and outreach program correct then the entire effort will suffer.

In our comments on the first draft of proposed regulations we stated that we thought the prohibition against promoting disposal options inconsistent with the purposes of the program, contained in PRC 42031.6(b), should be re-stated in the regulations. We still believe this would be wise because of experiences on the local level where stewardship organization websites linked to information on disposal that was unquestionably in conflict with the purposes of the program.

Conclusion

Thank you again for the opportunity to comment on the second draft proposed regulations. We are supportive of the direction in which the department is moving and believe that the second draft contains many improvements and ensures that this important program will effectively serve all Californians.

Sincerely,



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