



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Ricardo Sanchez, Public Member, Chairperson
Valerie Muñoz, Public Member, Vice Chairperson
Ryan Brooks, Public Member
Shirley Kim, Public Member
Debbie Veale, Licensee Member

The Communication and Public Education Committee met Oct. 11, 2018.

a. Discussion of a Proposal by the Chapman University School of Pharmacy Group to Require a Warning Label on Prescription Containers for Chemotherapy Medications

Attachment 1

Background

At the March 2017 committee meeting, students and faculty from Chapman University School of Pharmacy presented their research about proper handling and disposal of oral chemotherapy medications. The group proposed requiring a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

The group returned at the September 2017 committee meeting and presented early findings of a survey of health care professionals on the use and handling of oral chemotherapy drugs. The group also said it was preparing a similar survey for patients.

Committee Discussion

At the Oct. 11 committee meeting, Chapman faculty and students presented additional survey findings. A copy of their slide presentation is in **Attachment 1**.

The students surveyed 24 pharmacists and 12 patients about their knowledge, awareness and practices in handling and disposing of oral chemotherapy drugs. In summary, the findings indicated an important need for more education in these areas for pharmacists and patients.

Committee members expressed concern about the lack of public awareness and education revealed by the surveys. The committee suggested larger surveys with more respondents are needed to better understand the scope of the problem and possible solutions.

The students were urged to focus on increasing awareness and education about safe handling and drug disposal – rather than seeking a mandated requirement for adding a hazard symbol on prescription labels. Committee members also suggested advocates work with pharmacies that are willing to voluntarily add the hazard symbol to prescription labels.

The committee also directed staff to develop a possible policy statement by the board about proper handling and disposal of oral chemotherapy drugs. Staff will draft proposed language and return to the committee for review.

b. Update on the Proposal for a Public Service Billboard Message and Related Communications Materials on Prescription Drug Abuse

Attachment 2

Background

Outfront Media is donating five bulletin boards to the Board of Pharmacy for a public service message about prescription drug abuse. The committee approved a design created by board staff and chose “Use, Don’t Abuse” as the message theme.

The board reviewed the design and message in February 2018. A copy of the billboard is in **Attachment 2**.

Committee Discussion

At the Oct. 11 committee meeting, staff reported that a no-cost contract for five billboards has been sent to Outfront Media for approval and signature. As of Oct. 11, the board was waiting for Outfront to respond.

The committee directed staff to ask Outfront how long it would take to get the billboards printed and where they will be erected. Committee members said staff should use data on drug abuse to identify locations where the signs would be most effective. The executive officer said staff would try to get more information for the October board meeting.

c. Discussion of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information

Attachment 3

Background

In June 2017, the board adopted regulations for pharmacies and clinics to establish prescription drug take-back services. In July 2017, the board directed staff to develop consumer information on accessing drug take-back programs.

At the February 2018 board meeting, staff demonstrated an online search tool being developed to help consumers find locations for collection receptacles by city, ZIP code or pharmacy name.

Committee Discussion

At the Oct. 11 committee meeting, staff gave a brief demonstration of the completed online search tool on the board’s website. A total of 233 receptacle locations were registered with the board as of Sept. 25, 2018.

The new search tool includes only take-back locations that are registered with the board; it is not a comprehensive list of all take-back locations in California. Staff noted that the

board's website includes links to search tools for take-back locations operated by DEA, Don't Rush to Flush, and the California Department of Public Health.

Staff also reported the Department of Public Health has received \$3 million to fund grants to pharmacies for drug take-back services. The first grants could be awarded as soon as this month.

In addition, the Governor recently signed SB 212, which will require manufacturers and distributors of drugs or sharps to form stewardship programs to operate and pay for take-back programs for drugs and sharps. The law requires CalRecycle to promulgate regulations to implement the law by Jan. 1, 2021. A copy of SB 212 is in **Attachment 3**.

Staff advised the committee that the board will be involved with CalRecycle in developing the regulations for SB 212. Staff also said the new law will not change the board's current take-back regulations.

d. Update on the Development of Webinar Course to Satisfy the Education Requirement for Pharmacists to Furnish Naloxone

Background

Naloxone, a prescription drug that reverses opioid overdose, is one of the most effective tools for preventing overdose deaths from opioids. California law authorizes pharmacists to furnish naloxone to patients pursuant to a protocol adopted by the board in [California Code of Regulations, title 16, section 1746.3](#). The protocol requires pharmacists to complete one hour of training in an approved CE course before they can begin furnishing naloxone.

In February 2018, the board approved a recommendation by this committee to create a webinar course that will satisfy the naloxone training requirement. Pharmacists will be able to access the course on the board's website at their convenience.

Committee Discussion

At the Oct. 11 committee meeting, staff reported DCA's SOLID unit is finalizing the voice-over and closed-captioning. In addition, staff has asked SOLID to set up the webinar to prevent users from fast-forwarding through the video to the quiz at the end. The webinar is expected to be complete and available on the website in October.

Staff said the webinar quiz does not require a passing score. Instead, if a user chooses the wrong answer, the quiz indicates the answer is incorrect and shows the correct answer. Staff noted the Licensing Committee is looking into a possible requirement for users to earn a passing score on webinars. In addition, staff said technology could be used to prevent fast forwarding and to improve future versions of board webinars.

Staff also noted the webinar is intended mainly to help pharmacists meet the training requirement for furnishing naloxone, but the board may wish to offer CE as well to pharmacists who complete the course.

In public comment, Danny Martinez of CPhA said the Department of Health Care Services is expected to begin reimbursing Medi-Cal pharmacists for services performed under SB 493 as well as furnishing naloxone on April 1, 2019.

e. Discussion of Proposal to Establish a Twitter Account for the Board of Pharmacy

Attachment 4

Background

The board's 2017-2021 Strategic Plan calls for the board to "identify and use additional resources for public and licensee outreach services."

Committee Discussion

At the Oct. 11 committee meeting, staff proposed using Twitter as a communication tool for outreach to the public. It was noted that the board currently has several channels for communicating directly with licensees – including subscriber alerts, the newsletter, site inspections, etc. – but none that is widely accessible or known to the general public.

Staff gave a brief PowerPoint presentation about how the board could use Twitter effectively to

- Reach and engage consumers directly.
- Reach news media.
- Deliver timely information immediately.
- Create links with other organizations.
- Promote public awareness of the board's activities and brand.
- Increase public awareness and support for the board's mission and activities.

Staff also discussed types of information the board could communicate to the public via Twitter – including upcoming board meetings and events, recalls, regulations, news releases, and links to consumer resources. A copy of the PowerPoint presentation is in **Attachment 4**.

The committee expressed support for using Twitter as a communication channel with the public. Members noted that millions of Americans currently rely on Twitter to receive news and information, mostly on their cell phones, rather than traditional news media. Twitter messages also can easily be sent out in multiple languages.

The committee asked about using other social media in addition to Twitter, such as Facebook and Instagram. Staff recommended starting with Twitter because it is easiest to use. In addition, staff could collect and present data on its effectiveness to help the board determine whether to add other social media accounts.

In public comment, speakers said they supported the board using Twitter but expressed concern about how the board would handle hostile messages that target licensees or other

individuals. Speakers also asked if private messages sent on Twitter would be subject to Public Records Act requests. Counsel said these issues would require legal research.

Committee recommendation: Recommend that the board approve the establishment and use of a Twitter account to communicate with the public and direct staff to report on its usage in the committee's quarterly report to the board. In addition, direct staff to research other social media for possible use.

f. Discussion of Frequently Asked Questions Relating to Inventory Reconciliation Reports of Controlled Substances (California Code of Regulations, Title 16, Section 1715.65)

Attachment 5

Background

A major regulation adopted by the board to help pharmacies and clinics prevent drug losses and identify any losses early took effect April 1, 2018.

The new rule – [California Code of Regulations, title 16, section 1715.65](#) – requires pharmacies to perform a periodic inventory reconciliation for all controlled substances. The regulation also requires a physical hand count of all Schedule II drugs every three months. Many licensees have expressed questions about how to comply with the regulation.

Committee Discussion

At the Oct. 11 committee meeting, staff reported on steps being taken to help licensees understand and comply with the new regulation.

Staff has compiled and posted a list of [frequently asked questions \(FAQs\)](#) and answers on the board's website next to the regulation text. In addition, the FAQs were updated and published in the [July 2018 issue](#) of [The Script](#). A copy of the newsletter article is in **Attachment 5**.

Staff said a follow-up FAQ article is planned for the next [Script](#). In addition, staff provided training on the new regulation at a board-sponsored CE forum on Sept. 22 in Buena Park.

g. Discussion and Consideration of Granting CE Credit for Reading [The Script](#)

Background

In November 2017, the board directed the committee to discuss and consider awarding CE credit for reading [The Script](#). At the January 2018 committee meeting, members suggested pharmacists could earn one CE credit for reading each newsletter, up to a maximum of two credits per renewal cycle (every two years).

In February 2018, the board directed the committee to pursue options for awarding CE for [The Script](#) that would apply to the required two hours of board-provided CE in law and ethics every renewal cycle. The board also asked staff to research ways to keep costs and required staff time for the CE to a minimum.

Committee Discussion

At the Oct. 11 committee meeting, staff presented the following possible options for awarding CE for The Script:

- 1. Require pharmacists to self-certify reading The Script.** Users could click on a link in the newsletter that would take them to a site to certify they have read the newsletter. This option would require no staff time to prepare and minimal staff time to process the CE. **Estimated staff time to process each CE unit: one minute.**
- 2. Require pharmacists to pass a quiz to be included with The Script.** Users would answer multiple-choice or true-false questions based on articles. This option would require staff time to prepare questions and answers for articles. **Estimated staff time to process each CE unit: one minute.**
- 3. Require pharmacists to complete learning objectives after reading The Script.** Users would write a brief description of what they learned from reading articles. This option would require more technical capabilities and staff time to review responses. **Estimated staff time to process each CE unit: five to 15 minutes.**

The committee discussed the amount of staff time required to carry out the program and the need for ensure CE improves the professional competence of licensees. Staff said that developing quizzes for articles would not be an obstacle.

In public comment, speakers stressed the importance of having CE requirements that improve professional competence. It was suggested that staff invite pharmacy school faculty to write articles and quizzes for the newsletter.

Committee recommendation: Recommend that the board allow pharmacists who pass a quiz based on Script articles to earn one hour of CE credit per newsletter, up to a maximum of two credits per renewal period, as fulfillment of the two units of CE required to be earned from completion of board-provided CE to renew a pharmacist license.

h. Discussion and Consideration of FDA Guidance “Indications and Usage Section of Labeling for Human Prescription and Biological Products – Content and Format”

FDA regulations require a manufacturer’s drug labels to include an “Indications and Usage” section. This section must state the drug is indicated for the treatment, prevention, mitigation, cure or diagnosis of a disease or condition; or for the relief of the disease’s or condition’s symptoms.

In July 2018, the FDA issued a draft guidance for industry, “[Indications and Usage Section of Labeling for Human Prescription and Biological Products – Content and Format](#).” The guidance describes the FDA’s recommendations for how to clearly convey such information. A copy of the guidance document is in **Attachment 6**.

Staff presented the guidance document for the committee's information at the Oct. 11 meeting. There was no action or public comment.

i. Discussion and Consideration of Strategic Goals for the Communication and Public Education Committee

At the Oct. 11 committee meeting, members reviewed and discussed strategic goals for communication and public education as identified in the board's [Strategic Plan 2017-2021](#). A copy of the Communication and Public Education section of the strategic plan is in **Attachment 7**.

The committee recommended keeping the current goals. It was noted that activities and programs to carry out goals are still in progress. Members directed staff to provide updates on efforts to achieve the strategic goals at future committee meetings.

The committee asked staff to report annually on the Ask an Inspector program, including information about the number of calls and the top 10 questions received. Members also directed staff to report annually, beginning in January 2019, on the results of licensee surveys that are performed after pharmacy inspections.

j. Update and Discussion of Communication and Public Education Activities by Board Staff

1. The Script

Staff reported the next newsletter is expected to be published in October. It will include articles about the inventory reconciliation regulation, applying to be an inspector, counseling patients over 50 about opioids, the executive officer's retirement and new board members.

2. News Media

Staff reported the board's executive officer and public information officer participated in interviews or provided background in response to the following media inquiries:

- **Sacramento News and Review**, Feb. 15: Mike Mott, mandates for safe disposal of drug needles.
- **KPIX/CBS 5**, Feb. 26: Molly McCrea, PBM gag rules on pharmacists.
- **Kaiser Health News**, March 16: Pauline Bartolone, cease-and-desist order for Pharmedium Services LLC.
- **STAT**, March 21: Ed Silverman, cease-and-desist order for Pharmedium.
- **Capital Public Radio**, March 29: Sammy Caiolo, pharmacist use of CURES.
- **Oakland Tribune**, April 4: Harry Harris, arrest of RPH Jonathan Szkotak on suspicion of armed robbery at pharmacy.

- **KIQI/KATD**, April 18: Isabel Gutierrez, drug take-back programs.
- **KGTV/10News**, April 19: Adam Racusin, dispensing error statistics.
- **Capsa Healthcare**, May 3: Mike Stotz, new inventory reconciliation regulation.
- **Coach Lynn Radio Show**, May 15: Lynn Johnson, opioid epidemic and online drugs.
- **NBC4 Los Angeles**, June 1: Eric Leonard, stolen prescription pads from USC student health center.
- **San Diego Union-Tribune**, Aug. 7: Paul Sisson, lidocaine and drug shortages in California.
- **Palm Springs Desert Sun**, Aug. 10: Geraldine Estevez, availability of hormonal contraception.
- **KPIX**, Aug. 23: Julie Watts, Kaiser restriction on EpiPen prescriptions.
- **STAT**, Aug. 27: Ed Silverman, update on Pharmedium license cancellation.
- **News 10 San Diego**, Sept. 5: Jennifer Kastner, complaint about improperly stored Kaiser insulin.
- **Outpatient Surgery Magazine**, Sept. 20: Desiree Ifft, compounding regulations for ambulatory surgery centers.

3. Public Outreach

Staff reported the following public outreach activities by board inspectors and staff:

- March 5: Inspector Diann Potter presented information about the Board of Pharmacy and pharmacy technician education and regulations to high school students and adults in the Bakersfield Regional Occupational pharmacy technician program.
- March 14: Executive Officer Virginia Herold presented on pharmacy law, the Board of Pharmacy and corresponding responsibility to Touro University students.
- March 16: Supervising Inspector Janice Dang presented on the responsibilities of a PIC to fourth-year pharmacy students at Western University School of Pharmacy.
- March 16: Presentation by Executive Officer Virginia Herold at UOP Legislation Dinner.
- April 5: Presentation by Executive Officer Virginia Herold at CSHP's Peninsula Pharmacists Association.
- April 15: Presentation by Supervising Inspector Christine Acosta on California compounding regulations at Controlled Environment Testing Association (CETA)
- April 17: Presentation by Supervising Inspector Christine Acosta for webinar on implementing compounding regulatory changes for CHA
- May 3: Inspector Anna Kalantar presented California compounding regulations to San Fernando Valley Society of Health-Systems Pharmacists.
- May 21-22: Executive Officer Virginia Herold participated in a webinar presentation, "Advancing Quality Compounding – State Perspectives" at USP Workshop on Evolution and Advances in Compounding

- May 30: Executive Officer Virginia Herold presented a 2018 pharmacy law update to about 100 Ralphs pharmacy managers
- June 13: Executive Officer Virginia Herold presented the role of the Board of Pharmacy to about 150 pharmacy students at University of the Pacific.
- July 28: Executive Officer Virginia Herold, Chief of Enforcement Tom Lenox, and Supervising Inspector Tony Ngondara presented CE on Prescription Drug Abuse and Drug Diversion at California Northstate University.
- Aug. 7: Supervising inspectors Anne Hunt and De'Bora White provided training on 2018 pharmacy laws for the Competency Committee in Ontario.
- Aug. 14: Supervising Inspector Michael Ignacio presented an overview of the Board of Pharmacy, prescription drug abuse, drug take-back programs and pharmacist consultation to about 60 people at Eskaton Monroe Lodge Retirement Center in Sacramento.
- Aug. 14: Inspector Manisha Shafir spoke about new pharmacy laws to the Alameda County Pharmacists Association in Fremont.
- Sept. 5: Executive Officer Virginia Herald presented on the Board of Pharmacy to California Northstate University School of Pharmacy students.
- Sept. 8: Inspector Tran Song provided training on how to prepare for an inspection to pharmacists and pharmacy owners at the California Council for the Advancement of Pharmacy.
- Sept. 19: Executive Officer Virginia Herold presented on the Board of Pharmacy to Chapman University students.
- Sept. 22: Executive Officer Virginia Herold, Enforcement Chief Tom Lenox, Supervising Inspector Tony Ngondara and Inspector Steven Kyle presented on pharmacy law topics, drug diversion, corresponding responsibility and preparing for a board inspection to 167 pharmacists at CE training in Buena Park.
- Sept. 25-26: Executive Officer Virginia Herold presented regulations of outsourcing facilities and presented information about the FDA's proposed memorandum of understanding for interstate pharmacy shipments of compounded preparations at the FDA's 50-State Meeting in Washington, DC.
- Oct. 2-3: Executive Officer Virginia Herold represented the board at the NABP Executive Officers Fair
- Oct. 3-4: Executive Officer Virginia Herold attended the .Pharmacy quarterly meeting to discuss ongoing implementation of this internet program.
- Oct. 6: Executive Officer Virginia Herold presented 2019 new laws at the California Society of Health System Pharmacists annual meeting.

k. Review and Discussion of News or Journal Articles

Below are news articles on pharmacy issues that may be of interest to the board.

[Safety Violations Compound Pain Of Painkiller Shortages](#)

California Healthline

April 13, 2018

Safety violations at a major compounding pharmacy are exacerbating hospital shortages of key painkillers. In late March, **California’s Board of Pharmacy** barred the distribution of medications — including lidocaine and other local anesthetics — from a Texas factory belonging to the company, PharMEDium.

[Protecting your family from prescription errors](#)

10 News (San Diego)

April 26, 2018

Team 10 spent weeks sifting through disciplinary and enforcement actions taken against pharmacists and pharmacies. We discovered the **California Board of Pharmacy** issues hundreds of citations to pharmacists each year for dispensing errors, but errors are only what the state knows about.

[You can get birth control without a doctor's prescription in California, but there's a catch](#)

Desert Sun

Aug. 21, 2018

When it comes to this service, pharmacists are not obligated to provide prescriptions for contraceptives, but to do so, they must be trained. “The pharmacists have to complete a one-hour course available online, and then they’re licensed to do this,” said Becca Karpinski, Vice President of Strategy at Planned Parenthood of the Pacific Southwest. Yet this service isn’t available in every California pharmacy.

[State Board Of Pharmacy Investigating Kaiser EpiPen Policy](#)

KPIX

Aug. 23, 2018

After some parents were outraged at having to pay full price for half of the EpiPens Kaiser was providing to treat food and other allergies, state officials are investigating the situation. According to the FDA, a pharmacist could only reduce a prescription to one pen if that’s specifically what the doctor prescribed. “Generally, we would expect the pharmacy to fill it as it is written,” said Virginia Herold with the **California State Board of Pharmacy**.

I. Future Meeting Dates

The committee announced its meeting dates for next year:

- Tuesday, Jan. 8, 2019
- Wednesday, April 10, 2019
- Tuesday, June 25, 2019
- Wednesday, Oct. 9, 2019

Attachment 1

Safe Handling and Disposal of Oral Anticancer Chemotherapy

Chapman University School of Pharmacy (CUSP) Capstone Team
Irvine, California

PharmD Candidate 2020: Eric Dobberpuhl; Samantha Isidro; Dustin Le

PharmD Candidate 2019: Alexandra Corcoran; Priya Patel

PharmD Class of 2018: Ani Haroutunyan, PharmD; Thien Huynh, PharmD; Michael Phan, PharmD; Esther Shin, PharmD

Faculty Advisors: Coco Sun Yang, BPharm, MS, PhD; Siu-Fun Wong, PharmD



School of Pharmacy

Attachments - Page 2

We Propose:

The California Board of Pharmacy to include a standardized hazardous symbol on the main prescription label for the NIOSH designated hazardous drugs.

For Example:



How can our hazardous labelling proposal help?

1. Easy identification of hazardous drugs
2. Reminders for patients and caregivers
3. Promotion of proper and timely education
4. Heightening awareness of personnel throughout the process in drug handling and disposal



Our Efforts

1. Capstone Research Project at CUSP – Survey Studies:

- Assess knowledge, attitudes, and practice of handling and disposal of oral anticancer chemotherapy drugs:
 - Patients and Caregivers
 - Healthcare Providers
- Identify gaps and barriers in practice
- Goal: Propose best practice models for all stakeholders

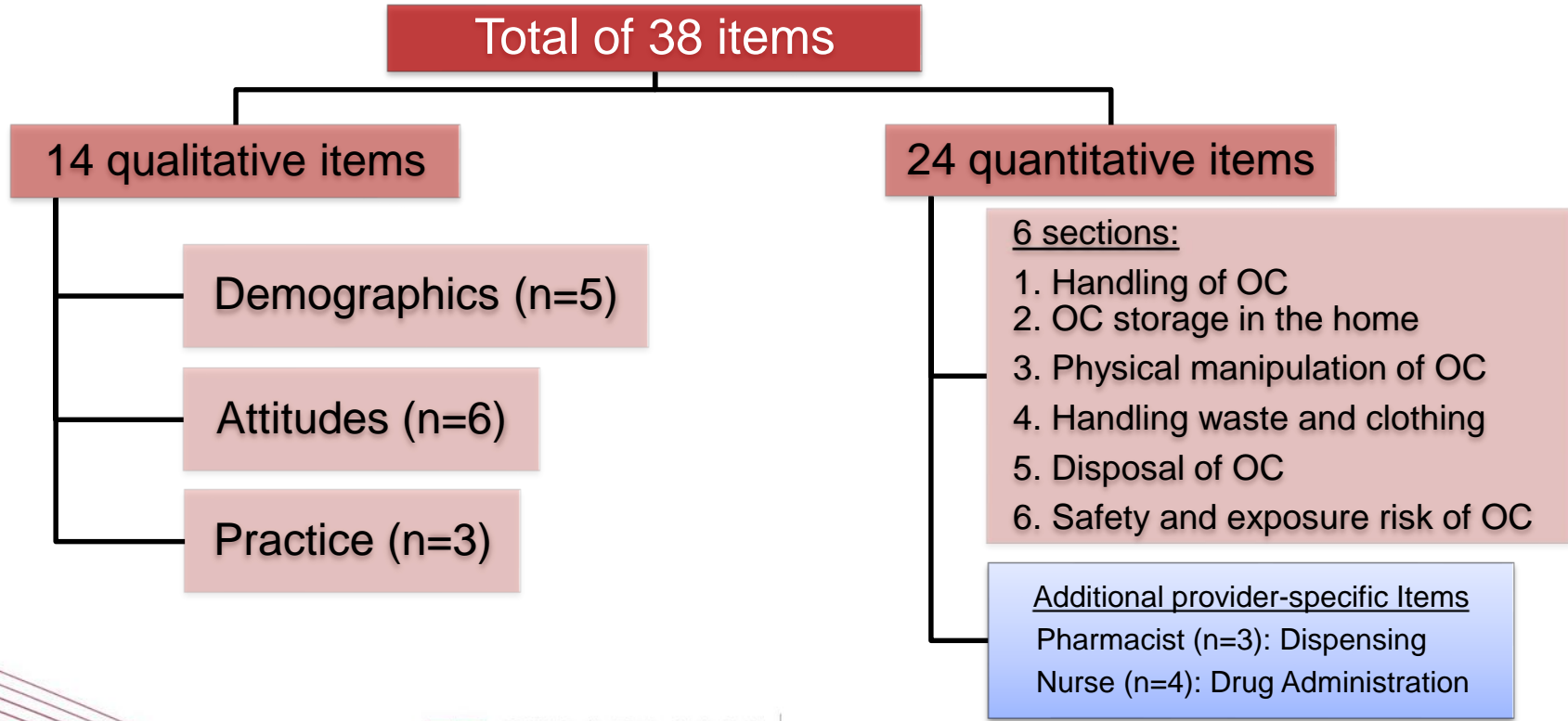
2. Policy Proposals to Professional Organizations

Proposal to the California Board of Pharmacy!

Survey Studies - Methodology

- A provider survey and a patient/caregiver survey were developed using literature review of current guidelines, recommendations, and state/federal law
- Following IRB approval, surveys were conducted via hard copy or electronic (Qualtrics)
- Subjects were recruited using either professional connections of providers and/or clinical sites, and the California Society of Health System Pharmacists membership outreach
- Data analysis: descriptive statistics were used

Methodology: Provider Survey



Results: Provider Survey – Demographics*

- # of pharmacists enrolled (n=24)
- # of oncology-trained (n=11)
- Years of practice
 - 0 to 2 (n=3)
 - 2 to 5 (n=4)
 - 5 to 10 (n=4)
 - 10 to 25 (n=7)
 - 25+ (n=6)
- Area of practice
 - Ambulatory care clinic/private practice office (n=1)
 - Community Pharmacy (n=1)
 - Hospital Inpatient pharmacy (n=15)
 - Hospital outpatient pharmacy (n=1)
 - Infusion center (n=1)
 - Oncology specialty practice (n=2)
 - Other (n=3)

*Combined data from direct contact pilot study and CSHP

Results: Provider Survey - Gaps

All Items						
	<u>Handling</u>	<u>Storage</u>	<u>Physical Manipulation</u>	<u>Handling of Waste</u>	<u>Disposal</u>	<u>Safety and Exposure</u>
Number Correct	78	57	20	123	47	82
Total Answers	96	72	24	192	72	96
Percent Correct	81%	79%	83%	64%	65%	85%
Number of items	4	3	1	8	3	3
Critical Items - contain contents in which 100% provider competency are desired						
	<u>Handling</u>	<u>Storage</u>	<u>Physical Manipulation</u>	<u>Handling of Waste</u>	<u>Disposal</u>	<u>Safety and Exposure</u>
Number Correct	46	20	20	62	37	N/A
Total Answers	48	48	24	96	48	N/A
Percent Correct	96%	42%	83%	65%	77%	N/A
Number of items	2	2	1	4	2	N/A

Comparative Data based on Years of Practice

Years of Practice	Percent Correct
0 to 2 years (n=3)	75%
2+ to 5 years (n=4)	57%
5+ to 10 years (n=4)	70%
10+ to 25 years (n=7)	78%
greater than 25 years (n=6)	83%

Continued education is warranted !!

Gaps & Barriers in Practice

- 2018 CUSP pilot study

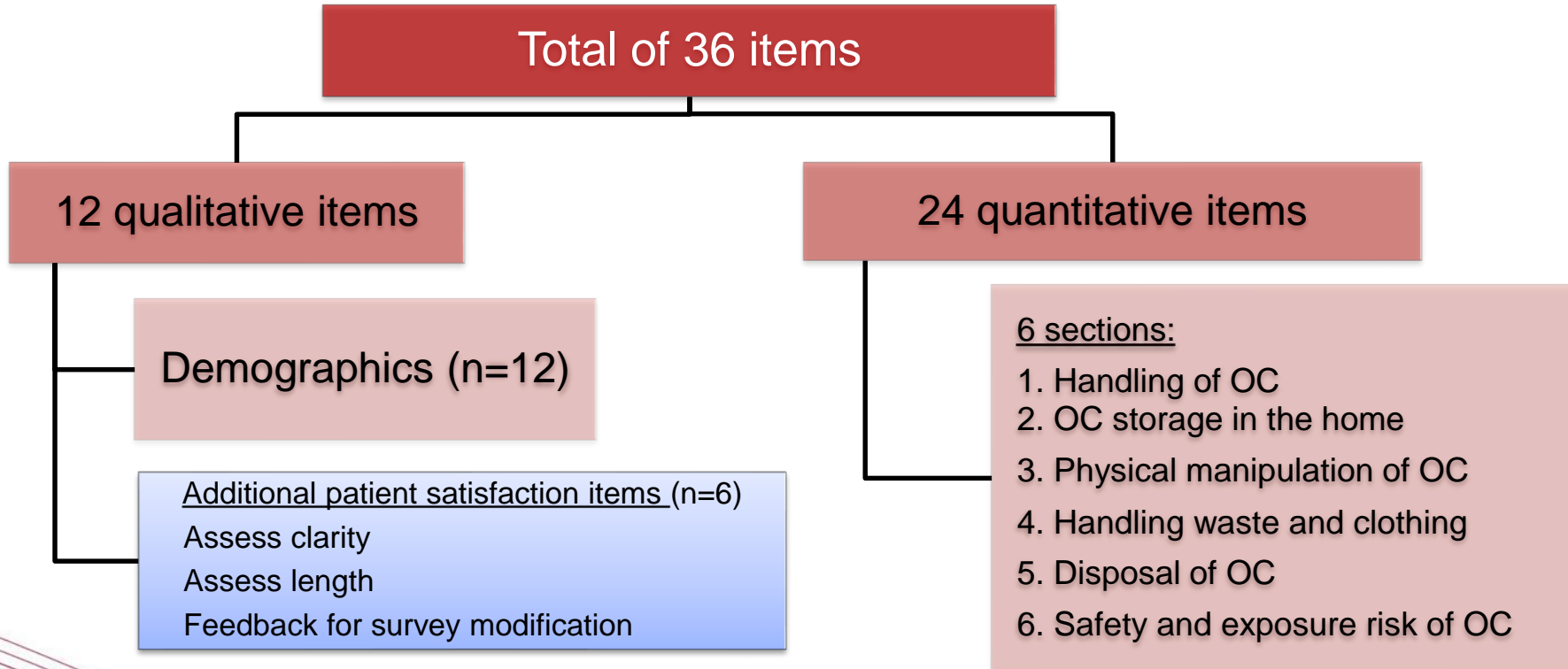
- Only 2/15 (13%) respondents indicated they routinely educate patients on disposal of oral chemotherapy, with 9 (60%) individuals only providing information on an as needed basis.

- 10/15 (66%) responders preferred to have the pharmacists as the primary patient educator compared to 4 (27%) responders for nurses and 1 (7%) for oncologists.

- Potential barriers identified in providing appropriate consultations include:
 - Insufficient resources (11/15, 73%)
 - Insufficient training (7/15, 47%)
 - Insufficient time (6/15, 40%)



Methodology: Patient Survey

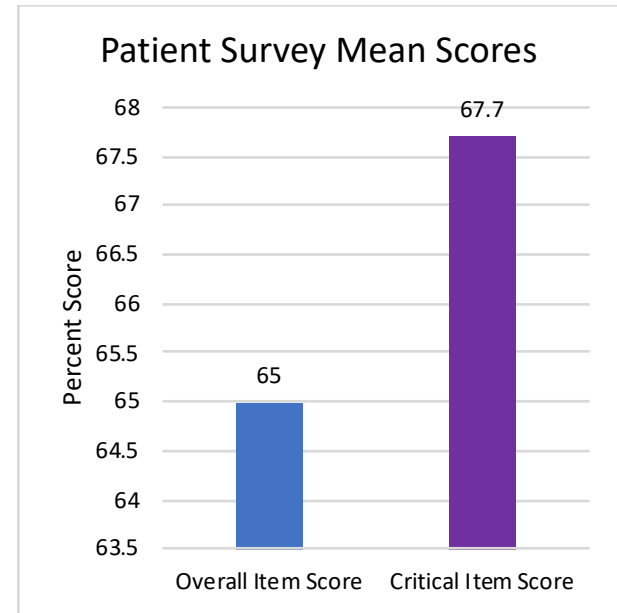


Results: Patient Survey - Demographics

- # of patients recruited (n=12)
 - Female (n=6)
 - Male (n=6)
- Educational background
 - High school (n=7)
 - College (n=3)
 - Graduate School (n=2)
- Vision problems (n=7)
- Hearing problems (n=1)
- Ethnic Background
 - White/Caucasian (n=8)
 - Latino/Hispanic/Spanish (n=1)
 - Asian/Asian American (n=3)
- Age range
 - 35-49 (n=1)
 - 50-64 (n=5)
 - 65-79 (n=3)
 - 80+ (n=3)

Results: Patient Survey – Gaps and Barriers

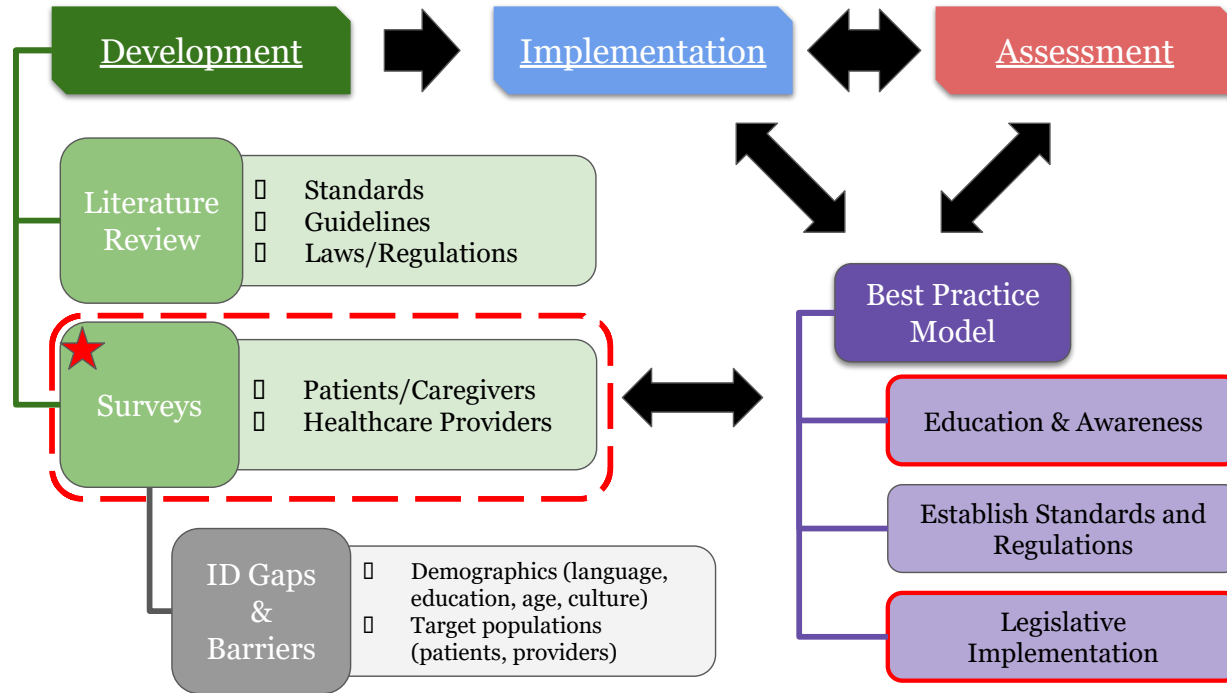
- **Highest score** in “Physical manipulation of OC” section = 100% (n=2 items)
- **Lowest score** in “OC Storage in the Home” section = 50% (n=3 items)
- 4/12 patients did not complete all items
 - Median 2 items skipped
 - Range: 1-12 items
 - Mean: 4.5 items
 - Demographics (**Potential Barriers?**)
 - Age range: 50-64 (n=3), 65-79 (n=1)
 - Vision problems (n=4)
 - White/Caucasian race (n=2), Asian American (n=2)
 - Male (n=2), female (n=2)
 - High school (n=3), graduate school (n=1)



In Summary...

- **Unsafe handling and improper disposal** became a public health issue that can impact the population at large for generations
- **The resources currently available** for the safe handling and proper disposal of hazardous agents in the home setting are suboptimal.
- Knowledge/awareness and practice of safe handling and disposal of OC are suboptimal based on the 24 statewide provider survey responses and 12 patient survey responses, **warranting continuing education.**
- An **automated alert system**, such as the addition of a hazardous drug symbol on the prescription label when such agents are dispensed is warranted.
- An **expansion of the drug take-back program** to include hazardous agents is critical in the establishment of a comprehensive safe handling and proper disposal program to protect the communities for many generations to come.
- There is a need to develop an **evidence-based best practice model** to empower practitioners in promoting safe handling and proper disposal of hazardous agents.

Quality Improvement Model: Master Plan



Attachment 2

Use, Don't Abuse

Safely Dispose of Unused Medications

Stop Prescription Drug Abuse



For more information visit: www.pharmacy.ca.gov



California State
Board of Pharmacy

Attachment 3

Senate Bill No. 212

Passed the Senate August 31, 2018

Secretary of the Senate

Passed the Assembly August 31, 2018

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2018, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add Chapter 2 (commencing with Section 42030) to Part 3 of Division 30 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 212, Jackson. Solid waste: pharmaceutical and sharps waste stewardship.

The California Integrated Waste Management Act of 1989, administered by the Department of Resources Recycling and Recovery (CalRecycle), generally regulates the disposal, management, and recycling of solid waste.

Former law, repealed as of January 1, 2013, required CalRecycle to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste, and to make the model programs available to eligible participants, as specified.

Existing law, the Medical Waste Management Act administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing regulations authorize pharmacies, hospitals or clinics with onsite pharmacies, distributors, and reverse distributors licensed by the California State Board of Pharmacy to offer, subject to prescribed requirements, specified prescription drug take-back services through collection receptacles or mail back envelopes or packages to provide options for the public to discard unwanted, unused, or outdated prescription drugs.

This bill would establish a stewardship program, under which a manufacturer or distributor of covered drugs or sharps, or other entity defined to be covered by the bill, would be required to establish and implement, either on its own or as part of a group of covered entities through membership in a stewardship organization, a stewardship program for covered drugs or for sharps, as applicable. The bill would impose various requirements on a covered entity or stewardship organization that operates a stewardship program, including submitting a proposed stewardship plan, an initial stewardship program budget, an annual budget,

annual report, and other specified information to CalRecycle. The bill would provide that all reports and records provided to CalRecycle pursuant to the bill are provided under penalty of perjury. By expanding the scope of the crime of perjury, the bill would impose a state-mandated local program. The bill would require proprietary information, as defined, submitted pursuant to the bill to be kept confidential.

The bill would require a stewardship plan for covered drugs to contribute to meeting specified minimum requirements for authorized collection sites in each county in which the plan will be implemented, including, as applicable, a minimum of one authorized collection site per 50,000 people in the county and a minimum of 5 collection sites in the county. The bill would authorize an operator of a stewardship program for covered drugs, if authorized by the department, after the stewardship plan has been approved, to establish a mail-back program or alternative collection program for covered products, or both, for a county in which it operates that does not have the minimum number of authorized collection sites, as specified. The bill would require a retail pharmacy to make a reasonable effort to serve as an authorized collector as part of a stewardship program for covered drugs and would require a retail pharmacy chain operating in a county to have at least one location or 15% of its store locations, whichever is greater, in the county serve as authorized collectors if the above-specified minimum authorized collection site requirements for the county are not met.

The bill would require each covered entity, either individually or through the stewardship organization of which it is a part, to pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates. The bill would also require a covered entity to pay a quarterly administrative fee in the amount adequate to cover any regulatory costs incurred by a state agency in administering and enforcing the provisions of the bill, to be deposited in the Pharmaceutical and Sharps Stewardship Fund, which the bill would create. The bill would authorize moneys in the fund to be expended, upon appropriation by the Legislature, for the regulatory activities of state agencies of administering and enforcing the bill.

The bill would authorize CalRecycle to impose an administrative penalty on a covered entity, program operator, stewardship

organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of the bill's provisions, to be deposited in the Pharmaceutical and Sharps Stewardship Penalty Account, which the bill would create.

The bill would require CalRecycle to adopt regulations for the administration of the bill's provisions, with an effective date of no later than January 1, 2021, and would authorize the state board to adopt regulations for the administration of the portions of these provisions for which it has been given responsibilities.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Chapter 2 (commencing with Section 42030) is added to Part 3 of Division 30 of the Public Resources Code, to read:

CHAPTER 2. PHARMACEUTICAL AND SHARPS WASTE
STEWARDSHIP

Article 1. Definitions

42030. For purposes of this chapter, the following terms have the following meanings:

(a) "Authorized collection site" means a location where an authorized collector operates a secure collection receptacle for collecting covered products.

(b) “Authorized collector” means a person or entity that has entered into an agreement with a program operator to collect covered drugs, including, but not limited to, any of the following:

(1) A person or entity that is registered with the United States Drug Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction.

(2) A law enforcement agency.

(3) A retail pharmacy that offers drug take-back services in compliance with Article 9.1 (commencing with Section 1776) of Title 16 of the California Code of Regulations.

(c) “Controlled substance” means a substance listed under Sections 11053 to 11058, inclusive, of the Health and Safety Code or Section 812 or 813 of Title 21 of the United States Code, or any successor section.

(d) “Cosmetic” means an article, or a component of an article, intended to be rubbed, poured, sprinkled, sprayed, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. “Cosmetic” includes articles with or without expiration dates.

(e) (1) “Covered drug” means a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State of California in any form, including, but not limited to, any of the following:

(A) Prescription and nonprescription drugs approved by the United States Food and Drug Administration pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or Section 351 of the federal Public Health Service Act (42 U.S.C. 262).

(B) A drug marketed pursuant to an over-the-counter drug monograph.

(C) A drug in a medical device, or a combination product containing a drug and a medical device.

(2) “Covered drug” does not include any of the following:

(A) Vitamins or supplements.

(B) Herbal-based remedies and homeopathic drugs, products, or remedies.

(C) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or any other

personal care product that is regulated as both a cosmetic and a nonprescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(D) A drug for which a pharmaceutical product stewardship program or drug takeback program is provided in the state as part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1.

(E) Biological drug products, as defined by 42 U.S.C. 262(i)(1), including those products currently approved in the state under a new drug application that will be deemed to be licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to Section 7002(e) of the federal Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148).

(F) A medical device, or a component part or accessory of a medical device, if it does not contain a covered drug.

(G) Drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals.

(H) Dialysate drugs or other saline solutions required to perform kidney dialysis.

(f) (1) (A) “Covered entity” means the manufacturer of covered products that are sold in or into the state.

(B) If no entity that meets the definition in subparagraph (A) is in the state, “covered entity” means the distributor of covered products that are sold in or into the state that is licensed as a wholesaler, as defined in Section 4043 of the Business and Professions Code, but does not include a warehouse of a retail pharmacy chain that is licensed as a wholesaler if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

(C) If no entity that meets the definition in subparagraph (A) or (B) is in the state, “covered entity” means a repackager, as defined in Section 4044 of the Business and Professions Code, of covered products that are sold in or into the state.

(D) If no entity that meets the definition in subparagraph (A), (B), or (C) is in the state, “covered entity” means the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered.

(E) If no entity that meets the definition in subparagraph (A), (B), (C), or (D) is in the state, “covered entity” means the importer of the covered products that are sold in or into the state.

(2) The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1).

(g) “Covered product” means a covered drug or home-generated sharps waste.

(h) “Department” means the Department of Resources Recycling and Recovery, and any successor agency.

(i) “Distributor” means a wholesaler, as that term is defined in Section 4043 of the Business and Professions Code.

(j) “Drug” means any of the following:

(1) An article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.

(4) A substance intended for use as a component of any substance specified in this subdivision.

(k) “Generic drug” means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance, characteristics, and intended use, though inactive ingredients may vary.

(l) (1) “Home-generated sharps waste” has the same meaning as defined in Section 117671 of the Health and Safety Code.

(2) “Home-generated sharps waste” does not include either of the following:

(A) Components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports.

(B) A biological product, as defined in Section 262(i)(1) of Title 42 of the United States Code, including a combination product, as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

(m) "Mail-back program" means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes as described in Section 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

(n) "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

(o) "Pharmacy" has the same meaning as defined in Section 4037 of the Business and Professions Code.

(p) "Prescription drug" means a drug, including, but not limited to, a controlled substance, that is required under federal or state law to be dispensed with a prescription, or is restricted to use by practitioners only.

(q) "Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this chapter.

(r) "Proprietary information" means information that is all of the following:

(1) Submitted pursuant to this chapter.

(2) A trade secret, or commercial or financial information, that is privileged or confidential, and is identified as such by the entity providing the information to the department.

(3) Not required to be disclosed under any other law or any regulation affecting a covered product or covered entity.

(s) "Retail pharmacy" means an independent pharmacy, a supermarket pharmacy, a chain pharmacy, or a mass merchandiser pharmacy possessing a license from the state board to operate a pharmacy.

(t) "Retail pharmacy chain" means a retail pharmacy with five or more stores in the state.

(u) "Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

(v) "State board" means the California State Board of Pharmacy.

(w) "Stewardship organization" means an organization exempt from taxation under Section 501(c)(3) of the federal Internal

Revenue Code of 1986 (21 U.S.C. 501(c)(3)) that is established by a group of covered entities in accordance with this chapter to develop, implement, and administer a stewardship program established pursuant to this chapter.

(x) “Stewardship plan,” or “plan” means the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization pursuant to this chapter.

(y) “Stewardship program” means a stewardship program for the collection, transportation, and disposal of covered products.

(z) “Ultimate user” means a state resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for his or her own use or for the use of a member of his or her household. “Ultimate user” does not include a needle exchange program established under Section 121349 of the Health and Safety Code, or a medical waste generator, as defined in Section 117705 of the Health and Safety Code.

Article 2. Covered Entities and Stewardship Organizations

42031. (a) (1) No later than 90 days after the effective date of this section, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board.

(2) A covered entity, or a stewardship organization on behalf of a group of covered entities, shall update the lists described in paragraph (1) and provide the updated lists to the state board on or before January 15 of each year or upon request of the department.

(b) No later than 90 days after the effective date of this section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the state board identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.

(c) The state board shall verify the information received pursuant to subdivisions (a) and (b) and make it available to the department upon request.

(d) The state board may issue a letter of inquiry to any entity listed in subparagraphs (A) to (E), inclusive, of paragraph (1) of

subdivision (f) of Section 42030. requesting a list of all drugs and sharps it distributes in California, regardless of whether the drugs or sharps are covered under this chapter, the name of the manufacturer of such products, and any additional information necessary to carry out this chapter. An entity that is issued a letter of inquiry pursuant to this subdivision shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the department, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this chapter, it shall submit all of the following to the state board in response to the letter of inquiry:

- (1) The basis for the claim that it is not a covered entity.
- (2) A list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale within the state.
- (3) If applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified pursuant to paragraph (2).
- (e) The state board shall obtain and verify and, within 30 days of receipt or upon request by the department, submit to the department a list of drugs and sharps sold or offered for sale in the state excluded from the definition of “covered drugs” pursuant to paragraph (2) of subdivision (e) of Section 42030 or excluded from the definition of “home-generated sharps waste” in subdivision (l) of Section 42030.
- (f) Notwithstanding Section 42036.4, information submitted by the state board to the department under this chapter may include proprietary information.
- (g) The state board shall notify the department if any covered entity or stewardship organization is in violation of this section for purposes of enforcement by the department.

42031.2. (a) The department shall adopt regulations for the implementation of this chapter with an effective date of no later than January 1, 2021.

(b) The state board may adopt regulations for the administration of the portions of this chapter for which it has been given responsibilities.

42031.4. (a) Except as specified in subdivision (d) of Section 42035, a covered entity is not in compliance with this chapter and is subject to penalties pursuant to Article 6 (commencing with

Section 42035) if, commencing one year from the adoption of regulations pursuant to Section 42031.2, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the department pursuant to Section 42032.

(b) In order to comply with the requirements of this chapter, a covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)).

42031.6. (a) A program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:

(1) Promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.

(2) Provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

(3) Establish an Internet Web site that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program.

(4) Prepare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste.

(5) Encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

(b) A program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program.

Article 3. Stewardship Plans

42032. (a) (1) Within six months of the adoption date of regulations by the department pursuant to Section 42031.2, a program operator shall submit to the department for approval a complete stewardship plan that meets the requirements of Section 42032.2 for the establishment and implementation of a stewardship program, in a format determined by the department.

(2) The department shall approve a proposed stewardship program if the program operator submits a completed plan that meets the requirements of this section.

(b) (1) Before submitting a stewardship plan to the department pursuant to this section, a program operator shall submit its proposed stewardship plan to the state board for review, and to any other applicable state agencies with areas of authority relative to the stewardship plan. The duration of time that the state board takes to review a stewardship plan pursuant to this paragraph shall not count toward the time limit specified in paragraph (1) of subdivision (a).

(2) An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the department.

(4) If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.

(c) (1) The department shall determine if a stewardship plan is complete, including the determinations required pursuant to subdivision (b), and notify the submitting program operator within 30 days of receipt.

(2) If the department finds that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan set forth in subdivision (d) shall commence upon the original date of receipt.

(3) If the department determines the stewardship plan is incomplete, the department shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.

(4) If the department determines upon resubmission that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

(d) (1) The department shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan.

(2) The department may consult with, or submit a stewardship plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the department takes to review a stewardship plan pursuant to this paragraph shall not count toward the 90-day time limit specified in paragraph (1).

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval.

(f) (1) If the department disapproves a submitted stewardship plan pursuant to subdivision (d), the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department.

(2) If the department finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this chapter until the program operator submits a plan that the department approves.

(g) A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program.

(h) If a stewardship plan is revoked pursuant to subdivision (a) of Section 42035.4 or terminated by the program operator that submitted the plan, a covered entity no longer subject to that plan may, without being subject to penalties pursuant to Article 6 (commencing with Section 42035), sell or offer for sale covered products in the state for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved stewardship plan to which the covered entity was subject.

(i) The department shall make all stewardship plans submitted pursuant to this section available to the public, except proprietary information in the plans protected pursuant to Section 42036.4.

42032.2. (a) (1) To be complete, a stewardship plan for covered drugs shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.

(B) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.

(C) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(D) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(E) Provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

(F) Provide for a collection system that complies with the requirements of this chapter and meets all of the following

requirements for authorized collection sites in each county in which the plan will be implemented:

(i) Provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.

(ii) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.

(iii) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

(G) Require a program operator to do all of the following:

(i) Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.

(ii) Provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(iii) (I) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. The authorized collection site shall maintain and make available to the department this documentation.

(II) An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.

(H) Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained and how, at a minimum,

instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

(2) Paragraph (1) shall apply only with regard to covered drugs.

(b) (1) At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

(2) A retail pharmacy shall make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

(3) A program operator shall include as an authorized collector under its stewardship program any entity listed in subdivision (b) of Section 42030 that offers to participate in the stewardship program, in writing and without compensation, even if the minimum convenience standards set in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) have been achieved. The program operator shall include the offering entity as an authorized collector in the program within 90 days of receiving the written offer to participate. A program operator shall not be required to respond to offers pursuant to this paragraph until the program operator's stewardship plan has been approved by the department.

(c) After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by the department, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control, by establishing one or both of the following:

(1) A mail-back program. The mail-back program may include providing information on where and how to receive mail-back materials or providing the locations at which it distributes prepaid, preaddressed mailing envelopes. The program operator shall propose the locations of those envelope distribution locations as part of the stewardship plan. Prepaid mailing envelopes may be mailed to an ultimate user upon request.

(2) An alternative form of collection and disposal of covered drugs that complies with applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(d) (1) To be complete, a stewardship plan for home-generated sharps waste shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered product sold or offered for sale by each participating covered entity.

(B) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(C) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(D) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws.

(E) Maintain an Internet Web site and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.

(F) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this chapter and that meets all the following requirements:

(i) 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 time period.

(I) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include information on proper sharps waste disposal.

(II) All sharps waste containers shall include on a label affixed to the container or packaging, or on a separate insert included in the container or packaging, the program operator's Internet Web site and toll-free telephone number.

(III) All sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging.

(ii) Upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility.

(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.

(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.

(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.

(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

(2) Paragraph (1) shall apply only with regard to home-generated sharps waste.

(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.

(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Article 4. Reports, Budgets, and Records

42033. With the submission of a stewardship plan, a program operator shall submit to the department an initial stewardship program budget for the first five calendar years of operation of its stewardship program that includes both of the following:

(a) Total anticipated revenues and costs of implementing the stewardship program.

(b) A total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period.

42033.2. (a) On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department both of the following:

(1) A written report describing the stewardship program activities during the previous reporting period of one year.

(2) A written program budget for stewardship program implementation for the upcoming calendar year.

(b) An annual report submitted pursuant to paragraph (1) of subdivision (a) shall include, at a minimum, all of the following for the prior year:

(1) A list of covered entities participating in the stewardship organization.

(2) The updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.

(3) The amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program.

(4) For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.

(5) For a stewardship plan for home-generated sharps waste, information on the mail-back program.

(6) Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.

(7) Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) How the program operator complied with all elements in its stewardship plan.

(9) Any other information the department reasonably requires.

(c) An annual program budget submitted pursuant to paragraph (2) of subdivision (a) shall include, at a minimum, both of the following for the upcoming calendar year:

(1) An independent financial audit of the stewardship program, as required by subdivision (b) of Section 42033.4, funded by the stewardship organization from the charge paid from its member covered entities pursuant to Section 42034 or by a covered entity if it operates its own stewardship program.

(2) Anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner.

(d) (1) The department shall determine if a submitted annual report and program budget are complete and notify the submitting stewardship organization or covered entity within 30 days.

(2) If the department finds that an annual report and program budget are complete, the department's 90-day review period for consideration of approval of the annual report and program budget, set forth in subdivision (e), shall commence upon the original date of receipt.

(3) If the department determines either an annual report or a program budget is incomplete, the department shall identify for the program operator within 30 days the required additional information, and the program operator shall submit a revised annual report or program budget, as applicable, within 30 days.

(4) If the department determines upon resubmission that the annual report or program budget is complete, the department's 90-day review period for consideration of approval of the annual report or program budget shall commence upon the date of receipt of the resubmitted report or program budget.

(e) (1) The department shall review the annual report and program budget required pursuant to this section and within 90 days of receipt shall approve, disapprove, or conditionally approve the annual report and program budget.

(2) (A) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall comply with the conditions of the conditional approval within 60 days of the notice date, unless the Director of Resources Recycling and Recovery determines that additional time is needed.

(B) If the department conditionally approves an annual report or program budget and the conditions are not met within 60 days of the notice date, unless additional time is granted pursuant to subparagraph (A), the department shall disapprove the annual report or program budget.

(3) If the department disapproves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

42033.4. (a) A program operator shall keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program.

(b) (1) The minutes, books, and records of a program operator shall be audited at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year.

(2) A program operator shall arrange for the independent certified public accountant audit to be delivered to the department, along with the annual report and program budget submitted pursuant to subdivision (a) of Section 42033.2.

(3) The department may conduct its own audit of a program operator. The department shall review the independent certified public accountant audit for compliance with this chapter and consistency with the program operator's stewardship plan, annual report, and program budget submitted pursuant to this chapter. The department shall notify the program operator of any conduct or practice that does not comply with this chapter or of any

inconsistencies identified in the department's audit. The program operator may obtain copies of the department's audit, including proprietary information contained in the department's audit, upon request. The department shall not disclose any confidential proprietary information protected pursuant to Section 42036.4 that is included in the department's audit.

42033.5. For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal pursuant to Section 42032.2, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator.

42033.6. As part of the administration of this chapter, within 12 months of a program operator's submission of three consecutive complete annual reports submitted pursuant to Section 42033.2, the department shall develop, and post on its Internet Web site, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, to the ultimate user.

Article 5. Financial Provisions

42034. In order to further the objective that covered entities establish and implement stewardship programs that comply with the requirements of this chapter, each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

42034.2. (a) (1) On or before the end of the 2022–23 fiscal year, and once every three months thereafter, a program operator shall pay to the department an administrative fee. The department shall set the fee at an amount that, when paid by every covered entity, is adequate to cover the department's and any other state agency's full costs of administering and enforcing this chapter. The total amount of fees collected shall not exceed the state's actual and reasonable regulatory costs to implement and enforce this chapter. These costs may include the actual and reasonable

costs associated with regulatory activities pursuant to this chapter before submission of stewardship plans pursuant to Section 42032.

(2) For a stewardship organization, the administrative fee paid pursuant to paragraph (1) shall be funded by the covered entities that make up the stewardship organization. This administrative fee shall be in addition to the charge paid pursuant to Section 42034. A stewardship organization may require its participating covered entities to pay the administrative fee and the charge paid pursuant to Section 42034 at the same time.

(b) The department shall deposit administrative fees paid by a program operator pursuant to subdivision (a) into the Pharmaceutical and Sharps Stewardship Fund, which is hereby established. Upon appropriation by the Legislature, moneys in the fund may be expended by the department, the state board, and any other agency that assists in the regulatory activities of administering and enforcing this chapter. Upon appropriation by the Legislature, moneys in the fund may be used for those regulatory activities and to reimburse any outstanding loans made from other funds used to finance the startup costs of the department's activities pursuant to this chapter. Moneys in the fund shall not be expended for any purpose not enumerated in this chapter.

42034.4. (a) (1) A stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization pursuant to Sections 42034 and 42034.2 to verify that the administrative fees and charges paid are proper and accurate. In addition, a stewardship organization may conduct an audit of authorized collectors to verify the charges submitted are proper and accurate.

(2) The purpose of the audits described in paragraph (1) is to ensure parties required by this chapter to pay or collect an administrative fee or charge are paying or collecting the proper amount to implement the program.

(b) If a stewardship organization conducts an audit pursuant to subdivision (a), it shall do all of the following:

(1) Conduct the audit in accordance with generally accepted auditing practices.

(2) Limit the scope of the audit of covered entities to confirming whether a charge or administrative fee has been properly paid by the covered entities.

(3) Hire an independent third-party auditor to conduct the audit.

- (4) Provide a copy of the audit to the department.

Article 6. Enforcement

42035. (a) (1) On or before June 30, 2022, and at least annually thereafter, the department shall post on its Internet Web site a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter.

(2) The state board shall coordinate with the department to verify that the list posted pursuant to paragraph (1) is consistent with the information submitted to each agency pursuant to Section 42031.

(b) A covered entity or stewardship organization that is not listed on the department's Internet Web site pursuant to subdivision (a), but demonstrates compliance with this chapter before the department is required to post the following year's list pursuant to subdivision (a), may request a certification letter from the department stating that the covered entity or stewardship organization is in compliance with this chapter. A covered entity or stewardship organization that receives a certification letter shall be deemed to be in compliance with this chapter.

(c) A distributor or wholesaler of covered products, and a pharmacy or other retailer that sells or offers for sale a covered product, shall monitor the department's Internet Web site to determine which covered entities and stewardship organizations are in compliance with this chapter. The distributor or wholesaler and the pharmacy or other retailer shall notify the department if it determines that a covered product that it sells or offers for sale is from a covered entity that is not listed on the department's Internet Web site.

(d) The sale, distribution, or offering for sale of any inventory that was in stock before the commencement of a stewardship program is exempt from this chapter and not required to be subject to a stewardship plan.

(e) If the department determines a covered entity or stewardship organization is not in compliance with this chapter, the department shall remove the entity from the list maintained on the department's Internet Web site pursuant to subdivision (a).

42035.2. (a) (1) The department may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.

(2) The amount of the administrative penalty imposed pursuant to this subdivision shall not exceed ten thousand dollars (\$10,000) per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed fifty thousand dollars (\$50,000) per day.

(b) The department shall not impose a penalty on a program operator pursuant to this section for failure to comply with this chapter if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.

(c) The department shall deposit all penalties collected pursuant to this section in the Pharmaceutical and Sharps Stewardship Penalty Account, which is hereby created in the Pharmaceutical and Sharps Stewardship Fund established in Section 42034.2. Upon appropriation by the Legislature, moneys in the Pharmaceutical and Sharps Stewardship Penalty Account may be expended by the department on activities including, but not limited to, the promotion of safe handling and disposal of covered products, grants for related purposes, and the administration and enforcement this chapter.

42035.4. Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this chapter, in addition to any other penalties authorized under this chapter, the department may take one or both of the following actions to ensure compliance with the requirements of this chapter, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:

(a) Revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

42035.6. (a) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following:

(1) Upon request, provide the department with reasonable and timely access, as determined by the department, to its facilities and operations, as necessary to determine compliance with this chapter.

(2) Upon request, provide the department with relevant records necessary to determine compliance with this chapter.

(b) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall maintain and keep accessible all records required to be kept or submitted pursuant to this chapter for a minimum of three years.

(c) All reports and records provided to the department pursuant to this chapter shall be provided under penalty of perjury.

(d) The department may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails to provide the department with the access to information required pursuant to this section, including one or both of the following:

(1) Imposing an administrative penalty pursuant to Section 42035.2.

(2) Posting a notice on the department's Internet Web site, in association with the list that the department maintains pursuant to paragraph (1) of subdivision (a) of Section 42035, that the covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this chapter.

(e) The department shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

42035.8. All handling, transport, and disposal undertaken as part of a stewardship program under this chapter shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

Article 7. Miscellaneous Provisions

42036. (a) Except as provided in subdivision (c), an action specified in subdivision (b) that is taken by a stewardship organization or a covered entity pursuant to this chapter is not a

violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code).

(b) Subdivision (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

(1) The creation, implementation, or management of a stewardship plan approved by the department pursuant to Article 3 (commencing with Section 42032) and the determination of the types or quantities of covered products collected or otherwise managed pursuant to a stewardship plan.

(2) The determination of the cost and structure of an approved stewardship plan.

(3) The establishment, administration, collection, or disbursement of the charge or administrative fee imposed pursuant to Section 42034 or 42034.2, respectively.

(c) Subdivision (a) shall not apply to an agreement that does any of the following:

(1) Fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the department and otherwise in accordance with this chapter.

(2) Fixes the output of production of covered products.

(3) Restricts the geographic area in which, or customers to whom, covered products are sold.

42036.2. (a) This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. If that ordinance is repealed in the jurisdiction or, if more than one ordinance is applicable, those ordinances are repealed in the jurisdiction, the drug or sharp shall be subject to this chapter in that jurisdiction within 270 days after the date on which the ordinance is, or ordinances are, repealed.

(b) This chapter shall preempt a local stewardship program for drugs or sharps enacted by an ordinance or ordinances with an effective date on or after April 18, 2018.

(c) A local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, may continue in operation, but the program and its participants shall not receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account, including, but not limited to, for administrative or enforcement costs. Participants of a local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, shall be eligible to participate in a stewardship program under this chapter and thereby become eligible to receive funds from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account only if the local stewardship program is dissolved.

42036.4. Proprietary information submitted to the department under this chapter shall be protected by all parties as confidential and shall be exempt from public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). The department and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 42036.4 to the Public Resources Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised, it is necessary that proprietary information collected for the purpose of administering a stewardship program be confidential.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2018

Governor

Attachment 4





Twitter

Creating an Effective a Communication Tool
For the Board of Pharmacy

How Can Using Twitter Benefit the Board of Pharmacy?

- 🐦 Reach and engage consumers.
- 🐦 Reach news media.
- 🐦 Deliver timely information.
- 🐦 Create links with organizations.
- 🐦 Promote Board activities/brand.
- 🐦 Increase public awareness/support.

What to Tweet?

-  Upcoming Board meetings/events.
-  Recalls.
-  Regulations.
-  News releases.
-  Links to consumer information.
-  Board news/photos.

Discussion and Consideration



Attachment 5

Inventory reconciliation regulation - FAQs

On April 1, 2018, a new board regulation took effect – California Code of Regulations, title 16, section 1715.65, [Inventory Reconciliation Report of Controlled Substances](#).

The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

As with any regulation, the board seeks compliance as early as possible. For the first few months, the board will focus on education to promote understanding of the regulation. During the transition, any inspection will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

Here is a summary of CCR section 1715.65 by subsection:

- (a) Requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190 ("clinics"), to perform periodic inventory and reconciliation functions for all controlled drugs. (Note: No frequency of these duties is specified in the regulation except for Schedule II drugs, which are discussed below.)
- (b) Requires the pharmacist-in-charge (PIC) or the clinic's consultant pharmacist to:
 - (1) Establish and maintain secure methods to prevent losses of controlled drugs.
 - (2) Establish written policies and procedures for performing reconciliation reports.
 - (3) Review all inventory and reconciliation reports.
- (c) Requires each pharmacy or clinic to prepare at least a **quarterly** inventory reconciliation report of all federal Schedule II medications, which is based on:



- (1) A physical count of all federal Schedule II medications at the time of each inventory.
 - (2) A review of all acquisition and disposition records since the last inventory.
 - (3) A comparison of 1 and 2 to identify any differences (losses or overages).
 - (4) Collection and retention of records to compile each inventory report.
 - (5) The report must identify the possible causes of overages.
- (d) Requires a pharmacy or clinic to file a report of losses and known causes to the board within 30 days of discovery or within 14 days if theft, self-use or diversion by a board licensee is the cause. If the cause is unknown, this section requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.
 - (e) Requires the inventory reconciliation report to be signed and dated by the individual(s) performing the inventory and countersigned by the PIC or professional director (for a clinic).
 - (f) Requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do a reconciliation report before leaving.

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Inventory reconciliation FAQs

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(g) For INPATIENT HOSPITAL PHARMACIES:
Requires a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.

(h) For any pharmacy servicing an AUTOMATED DRUG DELIVERY SYSTEM (regardless of location): Requires the PIC to:

- (1) Ensure that all controlled substances added to any automated drug delivery system are accounted for.
- (2) Ensure that access to any automated drug delivery system is limited to authorized facility personnel only.
- (3) Ensure that any discrepancy or unusual access to the controlled substances in the automated drug delivery system is evaluated.
- (4) Ensure that confirmed losses are reported to the board timely.

1. The regulation took effect April 1, 2018. Should I have performed my initial inventory beginning April 1, 2018?

No. The board expects pharmacies and clinics to transition to satisfy the inventory reconciliation requirements over a short period of time, but not necessarily by April 1. An initial physical count of the Schedule II medications is the first step.

2. Are there any drugs in addition to federal Schedule II controlled substances affected by the requirement to do a physical count and reconciliation each quarter?

No. The regulation requires a quarterly count and reconciliation of only federal Schedule II drugs. California and the federal government have separate controlled substances schedules, although there is much similarity between the two. Nevertheless, the board determined that the federal Schedule II drug list is more current and complete, and the federal list is the reference for reporting dispensing into

the Controlled Substances Utilization Review and Evaluation System (CURES) in California. A pharmacy may on its own add additional drugs to its reconciliation program.

3. Can a pharmacy or clinic estimate (instead of physically counting) federal Schedule II medications for the quarterly inventory?

No. A physical count of every Schedule II medication is required for the quarterly inventory reconciliation report.

4. Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?

No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of controlled medications to identify and prevent losses of Schedule III, IV and V drugs. The regulation only specifies the frequency of reconciliation duties for federal Schedule II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard of practice in the community under the circumstances of the pharmacy.

5. Does a perpetual inventory system satisfy the requirements of this regulation?

No. The use of a perpetual inventory system does not satisfy the regulation. The regulation requires both a physical count and reconciliation with all acquisitions and dispositions be performed every 90 days.

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Inventory reconciliation FAQs

Continued from page 7

6. If I use a perpetual inventory, can I use the physical counts made for the perpetual inventory instead of physically counting the drugs specifically for the inventory reconciliation report?

It depends. The regulation requires a physical count of each Schedule II medication every quarter, which is then used as part of the inventory reconciliation analysis and report. If, for example, the pharmacy or clinic physically counts the specific drug stock each time a Schedule II drug is dispensed or acquired, that count might be used to fulfill the physical count required by the inventory reconciliation regulation, but the PIC or consultant will need additional data. For any drug where there were no dispositions or acquisitions during the quarterly reconciliation period (and therefore no physical count through the perpetual inventory system), a physical count of the Schedule II drug must be made because each drug must be physically counted at least quarterly.

7. I have a recent physical count for each Schedule II drug. What do I compare that to? What do I do with that information?

For each medication, the PIC or consultant would start with the physical count of the medication from the last inventory reconciliation report and:

1. Add all acquisitions and subtract all dispositions that occurred during the reconciliation period (no greater than 90 days) to identify the amount of drug stock that should be on hand (expected drug stock).
2. Compare the expected drug stock to the actual physical inventory count.
3. If there is a difference, attempt to identify the source of overage or shortage. **NOTE:** If there is a discrepancy and the recent physical count is from a perpetual inventory

system, the board urges the facility to initiate a supplementary physical count of the medication. Determine if the facility needs to take corrective action, including modify its policies and procedures, conduct an investigation, institute additional security or modify its practices.

4. Whether or not there is a discrepancy, the results must be recorded in your inventory reconciliation report.

8. Does an inpatient hospital pharmacy or a pharmacy servicing onsite or offsite emergency kits (e-kits) have to complete an inventory reconciliation report for the Schedule II controlled substances contained within the e-kits?

There is no specific reconciliation report for the kits themselves, although a pharmacy's replenishment of Schedule II drugs removed from the emergency kits would be part of a pharmacy's disposition of medication.

9. An inventory reconciliation report of all Schedule II drugs shall be compiled at least every three months and, in order to complete the report, the inventory must be compared with a review of drugs that entered and left the pharmacy since the previous inventory reconciliation. Since no reconciliation report exists before April 1, 2018, does that mean that the first inventory reconciliation report will not be due before July 1, 2018?

To initiate the reconciliation process and establish a baseline for future inventory reconciliation reports, a physical count of all Schedule II medications must be undertaken. The board would generally expect a pharmacy to perform this count on or after April 1, 2018. To allow time to develop meaningful written policies and procedures for the inventory reconciliation process, the board recommends a pharmacy or clinic perform the inventory

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Inventory reconciliation FAQs

Continued from page 8

counts within the first 90 days after April 1 (i.e., July 1, 2018).

Additionally, any new PIC on or after April 1, 2018, is required to prepare a report upon assuming the PIC position. Within the first three months after April 1, 2018, the board would expect the new PIC, within 30 days, to have performed an inventory count of all Schedule II medications consistent with the requirements to prepare an inventory reconciliation report.

10. An initial inventory does not appear to be required as part of this rule change. Since a reconciliation report cannot be compiled without an initial reference count, would it be appropriate for pharmacies or clinics to perform a physical count of all Schedule II drugs during the initial three-month period (after April 1), and then begin reconciliation processes after July 1st?

Yes. See the response to question 9.

11. A PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1, 2018, how can the PIC create a reconciliation report, given there may not be a recent inventory or reconciliation report to refer to?

In this specific case, if prior data were unavailable because of the implementation date of the regulation, the board would expect the PIC to at least perform an inventory of all Schedule II medications consistent with the requirements to prepare the reconciliation report within 30 days (May 1, 2018).

12. Should the inventory reconciliation report encompass only significant losses, as defined by the DEA, or should the report encompass any discrepancy? If the former, doesn't a pharmacy's or clinic's filing of DEA Form 106 with the DEA already provide the requested information to the board if the board receives a copy of that report?

California law requires that any loss of controlled substances be reported to the board within 30 days – and reported within 14 days where drug theft, self-use or diversion have been committed by a board licensee. These are existing requirements, predating the inventory reconciliation requirements. The reconciliation regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board. Also, a separate report is required to the DEA (on a Form 106) of any significant loss of a controlled substance.

13. Will the board create a new process for reporting Schedule II controlled substances drug losses? Is there a standard form or email address to submit this information?

The board will not create a new or additional process for reporting the loss of controlled substances. A DEA Form 106 or a written statement containing specified details of the loss is sufficient. Check the board's website on [how to report a drug theft or loss](#).

14. If my pharmacy or clinic is unable to identify the cause of the loss, should we wait to report the loss to the board until the cause is determined?

No. Reporting is required for any loss of controlled substances within, at most, 30 days regardless if a cause of the loss was identified. Should a cause be identified later, an additional report can be made to the board. If the cause is theft, diversion or self-use by a board licensee, the report must be made within 14 days.

However, the regulation also directs that "further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substance" where the source of a loss cannot be readily identified.

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Inventory reconciliation FAQs

Continued from page 9

15. Does a pharmacy have to maintain actual paper documents of the records used to compile each inventory reconciliation report? Are electronic records acceptable?

All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. Provided the records are readily retrievable, electronic records are acceptable.



16. Can the inventory reconciliation report be completed by multiple persons?

Yes. All persons involved in performing the inventory must sign and date the report, which also must be countersigned by the PIC or professional director (if a clinic).

17. How do I physically count liquid Schedule II medications for the reconciliation report?

The board does not expect a count or measurement of every liquid you have as part of the quarterly reconciliation. Instead, the board recommends:

- **Where there is a unit of use container,** a pharmacist should accept the measurement printed on the container and include it in the physical count. However, if the unit of use container looks damaged or altered in some manner, treat the item as quarantined.
- **Where multidose containers are used,** a pharmacist should subtract the amount dispensed from the measurement printed on the container. Subsequently, the pharmacist should document the

remaining amount on the container itself. Example: A pharmacist dispensed 240ml from a 473ml stock bottle. The pharmacist would subtract 240ml from 473ml and document the difference of 233ml on the stock bottle. The remaining amount of 233ml would be used as the physical count for the reconciliation report.

18. Can unlicensed personnel (e.g., clerks) perform the inventory necessary to complete the inventory reconciliation report?

As identified in CCR section 1793.2, the counting of pharmaceuticals is considered a “nondiscretionary task” – a duty a pharmacy technician may perform. Accordingly, unlicensed personnel cannot complete the inventory function.

Attachment 6

Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Iris Masucci at 301-796-2500 or (CBER) the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**July 2018
Labeling**

Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

Guidance for Industry

Additional copies are available from:

*Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

and/or

*Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**July 2018
Labeling**

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1 **Indications and Usage Section of Labeling for Human Prescription**
2 **Drug and Biological Products – Content and Format**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
11

12
13
14 **I. INTRODUCTION**
15

16 This guidance is intended to assist applicants in drafting the INDICATIONS AND USAGE
17 section of labeling as described in the regulations for the content and format of labeling for
18 human prescription drug and biological products² (21 CFR 201.57(c)(2)).³
19

20 Recommendations include the following:
21

- 22 • General principles to consider when drafting the INDICATIONS AND USAGE section
23 of the labeling
- 24 • What information to include in the INDICATIONS AND USAGE section
- 25 • When to include additional descriptors or qualifiers as part of the indication in the
26 INDICATIONS AND USAGE section
- 27 • When to include additional descriptors or qualifiers as part of the indication in the
28 INDICATIONS AND USAGE section
- 29 • When to include limitations of use in the INDICATIONS AND USAGE section
- 30 • When to include limitations of use in the INDICATIONS AND USAGE section
- 31

¹ This guidance has been prepared by the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

² This guidance applies to drugs, including biological drug products. For the purposes of this guidance, *drug product* or *drug* will be used to refer to human prescription drug and biological products that are regulated as drugs, except when there is a difference in the regulation. In such cases, *biological products* will be used. This guidance does not apply to those biological products that are also devices.

³ See the final rule “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” (71 FR 3922, January 24, 2006) and additional labeling guidances at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

- How to write, organize, and format the information within the INDICATIONS AND USAGE section

The purpose of this guidance is to help ensure that the INDICATIONS AND USAGE section is clear, concise, useful, and informative and, to the extent possible, consistent within and across drug and therapeutic classes. Applicants should follow the recommendations in this guidance when developing the INDICATIONS AND USAGE section for a new drug and when revising this section for a currently approved drug, including when seeking approval of a new indication.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. GENERAL PRINCIPLES

The primary role of the INDICATIONS AND USAGE section of labeling is to enable health care practitioners to readily identify appropriate therapies for patients by clearly communicating the drug's approved indication(s). Among other information, the INDICATIONS AND USAGE section states the disease or condition, or manifestation or symptoms thereof, for which the drug is approved, as well as whether the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of that disease or condition, including relief of symptoms (21 CFR 201.57(c)(2)). Other sections of labeling (e.g., DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, USE IN SPECIFIC POPULATIONS), as applicable, also provide essential details that enable safe and effective use of a drug, and labeling should be considered in its entirety for individual prescribing decisions.

To comply with the general labeling requirements in 21 CFR 201.56 and 201.57, the INDICATIONS AND USAGE section must:

- Reflect the scientific evidence accurately
- Be concisely written to include the information necessary to clearly convey the use(s) for which the drug has been shown to be safe and effective
- Use terminology that is clinically relevant and scientifically valid and understandable to health care practitioners

Additionally, indications that are straightforward, clear, concise, and consistently written will facilitate the indexing of indications in electronic drug databases. This may, in turn, assist health care practitioners in searching indications in electronic medical information systems, thereby providing easier access to the information in FDA-approved labeling needed for clinical decision making.

78 **A. Scope of the Indication(s)**
79

80 Governing regulations articulate parameters for the evidentiary standard necessary for an
81 indication to be listed in the INDICATIONS AND USAGE section of labeling. For drug
82 products other than biological products, absent an applicable waiver, “all indications listed in the
83 INDICATIONS AND USAGE section must be supported by substantial evidence of
84 effectiveness based on adequate and well-controlled studies” as defined in 21 CFR 314.126(b)
85 (§ 201.57(c)(2)(iv)).⁴ For biological products, indications “must be supported by substantial
86 evidence of effectiveness” (§ 201.57(c)(2)(v)). Any statements in this section of the labeling
87 comparing the safety or effectiveness of drug or biological products with other agents for the
88 same indications must be similarly supported – that is, for drugs, they must be supported by
89 substantial evidence of effectiveness based on adequate and well-controlled studies and, for
90 biological products, they must be supported by substantial evidence of effectiveness
91 (§ 201.57(c)(2)(iii)).

92
93 Pursuant to the governing regulations, “[i]ndications or uses must not be implied or suggested in
94 other sections of the labeling if not included” in the INDICATIONS AND USAGE section
95 (§ 201.57(c)(2)(iv) and (v)). However, FDA may require a specific warning relating to an
96 unapproved use in the WARNINGS AND PRECAUTIONS section of the labeling if the drug is
97 commonly prescribed for a disease or condition and if such usage is associated with a clinically
98 significant risk or hazard (§ 201.57(c)(6)(i)).⁵
99

100 **I. Scope of an Indication Relative to the Population Studied**
101

102 The INDICATIONS AND USAGE section should clearly communicate the scope of the
103 approved indication, including the population to which the determination of safety and
104 effectiveness is applicable. The indicated population may mirror the studied population, for
105 example, in terms of patient demographics or severity of disease or condition, but can sometimes
106 differ. In some cases, FDA’s expert reviewers may fairly and responsibly conclude, based on
107 their scientific training and experience, that the available evidence supports approval of an
108 indication that is broader or narrower in scope than the precise population studied.⁶ Applicants
109 should discuss the scope of a proposed indication with the applicable review division.⁷
110

111 Indications may be written to include certain patient populations that may have been absent or
112 specifically excluded from the clinical studies that supported approval (e.g., geriatric patients,

⁴ The Director of CDER may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in 21 CFR 314.126(b) with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. A waiver petition must explain why the study, as conducted, will still yield substantial evidence of effectiveness (see 21 CFR 314.126(c)). Additionally, an applicant may submit a request to the Director of CDER or the Director of CBER asking for a waiver of any requirement under 21 CFR 201.56, 201.57 or 201.80 (see 21 CFR 201.58).

⁵ See the guidance for industry *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format*.

⁶ See generally 21 U.S.C 355(d).

⁷ See 21 CFR 312.41.

113 pregnant women, patients taking certain concomitant drugs, patients with a different severity or
114 stage of a disease). An indication for a broader population than the patient population studied in
115 controlled trials may be appropriate after careful consideration of the generalizability of the
116 evidence, consistencies in the disease process across different groups, and the drug's overall
117 benefits and risks.

118
119 For example, if a study evaluating a drug in adults enrolled patients of a certain age range and
120 excluded patients taking certain concomitant drugs, and available evidence does not suggest the
121 drug would be unsafe or ineffective in adult patients outside that age range or in those taking the
122 other drugs, the indication should be worded to reflect the broader age group (i.e., "in adults")
123 rather than the exact ages studied. In addition, unless available evidence suggests otherwise, the
124 indication should not exclude use in patients taking the concomitant drugs. Recommendations
125 regarding age groups outside of an adult population are discussed in section II.A.2.

126
127 Similarly, if a drug were studied only in patients with a moderate form or stage of a disease and
128 there is reason to believe, based on the generalizability of the data, consistencies in the disease
129 process, and the drug's benefits and risks, that the drug would be both safe and effective in a
130 broader group with the condition, an indication covering the broader population may be
131 appropriate. In some cases, an indication covering the overall disease population can be
132 considered. Specifics regarding the patient population studied should be described in the
133 CLINICAL STUDIES section of the labeling.

134
135 Conversely, an indication may be approved for a population narrower than that which was
136 studied. For example, a study may enroll and randomize patients, but then stratify participants
137 by the presence or absence of a specific genomic marker. If the study demonstrated benefit only
138 in patients who had tested positive for the marker, FDA's expert reviewers may fairly and
139 responsibly conclude, based on their scientific training and experience, that the available
140 evidence supports approval of an indication in a population that is narrower in scope than the
141 population that was studied.⁸

142
143 There may also be circumstances in which the indication should reflect the precise population
144 studied. For example, some study designs such as prognostic enrichment strategies (e.g.,
145 enrolling only people with a prior myocardial infarction in a study examining the effects of an
146 antiplatelet drug) and most predictive enrichment strategies (e.g., enrolling only people with a
147 specific genomic marker) may identify the population in which the benefits outweigh the risks or
148 the only population in which effectiveness is reasonably likely.⁹ In such cases, the indication
149 should reflect only the population studied, unless and until evidence becomes available to
150 support a determination that broader safety and effectiveness can be expected.

151
152 2. *Age Groups in Indications*
153

⁸ See generally 21 USC 355(d).

⁹ See the draft guidance for industry *Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products*. When final, this guidance will represent FDA's current thinking on this topic.

154 Approval of a drug in pediatric patients¹⁰ is generally based on sufficient data from studies in the
155 following populations:

156

157 • A pediatric population only

158

159 • Both adult and pediatric populations

160

161 • Adults, with supporting data in a pediatric population (e.g., safety,
162 pharmacokinetic data) that allow extrapolation of effectiveness to a pediatric
163 population¹¹

164

165 • One pediatric population that allows extrapolation of effectiveness to another
166 pediatric population¹²

167

168 In certain circumstances (see section II.A.1), it may be appropriate to consider an indication for
169 an adult population in an age group broader than the population that was studied. However, this
170 approach is generally not appropriate across pediatric populations or between adult and pediatric
171 populations because of the statutory requirements related to pediatric assessments¹³ and the
172 unique clinical considerations for pediatric patients. For example, pediatric patients may
173 metabolize drugs differently from adults (in an age-related manner), are susceptible to different
174 safety risks, and often require different dosing regimens even after correction for weight.

175

176 For these reasons, age groups should be included in indications. As such, an indication should
177 state that a drug is approved, for example, “in adults,” “in pediatric patients X years of age and
178 older,” or “in adults and pediatric patients X years of age and older.”

179

180 Applicants should discuss the scope of and age groups for a proposed indication with the
181 applicable review division.¹⁴

¹⁰ The labeling regulations define *pediatric patients* as those ranging in age from birth through 16 years (21 CFR 201.57(c)(9)(iv)).

¹¹ Although it may be appropriate to extrapolate effectiveness, it is generally not appropriate to extrapolate safety with respect to pediatric populations.

¹² See section 505B(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 201.57(c)(9)(iv). See also the draft guidance for industry and review staff *Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling*. When final, this guidance will represent FDA’s current thinking on this topic.

¹³ The Pediatric Research Equity Act (Public Law 108-155) generally requires certain applications for, among other things, a new indication to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. Pediatric assessments “shall contain data, gathered using appropriate formulations for each age group for which the assessment is required that are adequate (i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and (ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective” (section 505(B)(a) of the FD&C Act).

¹⁴ See 21 CFR 312.41.

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B. Distribution of Information Among Labeling Sections

Generally, the section of the full prescribing information to which particular drug information is most relevant will contain the most detailed discussion of such information. Other sections should discuss only those aspects of the information that are pertinent to those other sections' scopes and purposes. There may be instances when it is necessary to include information in the INDICATIONS AND USAGE section that is discussed in greater detail elsewhere in the labeling. For example, the INDICATIONS AND USAGE section may include a limitation of use that has a cross-reference to a more detailed discussion of the information supporting the limitation in the WARNINGS AND PRECAUTIONS section (see section III.B). Because detailed information about topics such as clinical studies and risks related to limitations of use will generally be found elsewhere in the labeling, the information in the INDICATIONS AND USAGE section should be concise.

C. Updating the INDICATIONS AND USAGE Section

The INDICATIONS AND USAGE section “must be updated when new information becomes available that causes the labeling to be inaccurate, false, or misleading” (§ 201.56(a)(2)).¹⁵ In addition, it is appropriate in certain circumstances for application holders to update this section to reflect current practices for writing indications for a particular group of drugs (for example, when more information becomes available about the drug, drug class, or specific disease or when the endpoints become better established). Application holders should review the INDICATIONS AND USAGE section regularly to ensure that it reflects current science and, to the extent possible, maintains consistency within a pharmacologic or therapeutic class.¹⁶

III. CONTENT AND FORMAT OF THE INDICATIONS AND USAGE SECTION

The INDICATIONS AND USAGE section includes the indication and, as appropriate, any identified limitations of use.¹⁷ The INDICATIONS AND USAGE section “must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition” (§ 201.57(c)(2)). When drafting the INDICATIONS AND USAGE section, applicants should consider what information is needed to clearly convey the approved indication and whether other information in addition to the identification of the disease or condition is warranted.

For many drugs, the indication will be sufficiently conveyed by stating the disease or condition being treated, prevented, mitigated, cured, or diagnosed, and the approved age group(s) (see section II.A.). For example, indications may be straightforward for many conditions (e.g.,

¹⁵ Application holders update their labeling using the procedures in 21 CFR 314.70 or 601.12, as applicable.

¹⁶ See generally 21 CFR 201.56(a).

¹⁷ See 21 CFR 201.57(c)(2).

223 symptomatic conditions such as pain, allergic rhinitis). In such circumstances, endpoints and
224 descriptions of benefit should be summarized in the CLINICAL STUDIES section of labeling
225 and should not be included in the indication.

226
227 On the other hand, other scenarios may warrant the inclusion of more information in the
228 indication. Such scenarios could include cases in which a drug may target different aspects of a
229 disease (e.g., in multiple sclerosis) or cases where endpoints are not well-standardized (e.g., in
230 heart failure); in these scenarios, the specific benefits of the drug should be stated. For example,
231 for a drug indicated for the treatment of insomnia, the indication should state whether the drug
232 affects sleep onset, sleep maintenance, or both, in order to facilitate appropriate prescribing for
233 an individual patient. Similarly, for many outcome studies, when there is an overall effect on a
234 composite endpoint, the indication should identify the components of the composite (e.g.,
235 cardiovascular death, myocardial infarction, and stroke). In such cases, it would be critical to
236 clearly state in the indication what benefit the drug has been shown to convey (see
237 section III.C.1).

238
239 Details of studies that describe the basis for approval (e.g., “Effectiveness was demonstrated in
240 two 12-week trials in patients with FEV₁ less than 60% of predicted.”) should not be included in
241 the INDICATIONS AND USAGE section. This section is not intended to be a description of the
242 data supporting the determination of effectiveness, and the inclusion of such statements here
243 could have the unintended consequence of inappropriately limiting use of the drug in practice
244 (e.g., inadvertently suggesting short-term use of a drug indicated for a chronic condition).
245 Likewise, discussions of disease definitions (e.g., diagnostic criteria for major depressive
246 disorder) should not be included. These types of details should be discussed in the CLINICAL
247 STUDIES section of labeling (see section III.C.1).

248
249 Specific components of and other considerations for the INDICATIONS AND USAGE section
250 are discussed in detail in sections A through D below.

251

252 **A. Indication**

253

254 The indication should begin “DRUG-X is indicated” and must include the following elements
255 required under 21 CFR 201.57(c)(2)(i):

256

- 257 • The disease, condition, or manifestation of the disease or condition (e.g., symptom(s))
258 being treated, prevented, mitigated, cured, or diagnosed
- 259
- 260 • When applicable, other information necessary to describe the approved indication (e.g.,
261 descriptors of the population to be treated, adjunctive or concomitant therapy, or
262 specific tests needed for patient selection)
- 263

264

265 The following subsections provide details on each element of an indication listed above, along
266 with illustrative examples demonstrating how to draft these elements so they are clear, concise,
267 and easily identifiable and searchable.

267

268 1. *The Disease, Condition, or Manifestation Being Treated, Prevented, Mitigated,*
269 *Cured, or Diagnosed*
270

271 The INDICATIONS AND USAGE section must state that the drug “is indicated for the
272 treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a
273 manifestation of a recognized disease or condition, or for relief of symptoms associated with a
274 recognized disease or condition” (§ 201.57(c)(2)). The disease, condition, or manifestation
275 should be included in the indication using high-level terms that are clinically relevant and
276 scientifically valid (e.g., asthma, diabetes mellitus, pain). Although FDA does not endorse any
277 particular resource for terms used to describe diseases, conditions, or symptoms, all terminology
278 should be well understood and easily recognizable by health care practitioners.
279

280 2. *Other Information Necessary To Describe the Approved Indication*
281

282 In addition to identifying the disease, condition, or symptom for which the drug is approved,
283 there may be additional critical aspects of an indication that are important to include. Examples
284 of such situations are described in items a through c below.
285

286 a. Selected patient subgroups or disease subpopulations for whom the drug is
287 approved
288

289 In some cases, additional descriptors or qualifiers are critical to include as part of the indication
290 to clearly identify the patient population for whom the drug is approved. In addition to including
291 the approved age group(s) (see section II.A.2), other circumstances in which such additional
292 information would be important include, but are not limited to, indicating a drug for patients
293 previously treated with other therapies (e.g., hormone-refractory prostate cancer), patients with a
294 certain classification of a disease (e.g., World Health Organization Group I pulmonary arterial
295 hypertension), or patients with other important identifying variables (e.g., immunocompetent
296 patients). For example, if a drug is for use only in patients with a history of coronary disease
297 events (i.e., as secondary prevention), the indication should clearly convey the patient population
298 for which the drug is approved.
299

300 If evidence is available to support the safety and effectiveness of the drug only in selected
301 subgroups of the larger population with the target disease or condition, “this section must
302 include...a succinct description of the limitations of usefulness” (§ 201.57(c)(2)(i)(B)). Thus,
303 the indication should include information on the subgroup(s) for whom the drug is approved.
304 For example:
305

- 306 • DRUG-X is indicated for the treatment of adult and pediatric patients 12
307 years of age and older with moderate to severe plaque psoriasis who are
308 candidates for phototherapy or systemic therapy.
309

310 If a drug should be reserved for use in specific situations (e.g., cases refractory to other drugs)
311 because of safety concerns, “this section must include...a statement of the information”
312 pertaining to such situations (§ 201.57(c)(2)(i)(E)). For example:
313

- 314 • DRUG-X is indicated for the treatment of moderate to severe active
315 rheumatoid arthritis in adult patients who have had an inadequate response
316 to TNF antagonist therapy.

317
318 For drugs approved for use only after other drug therapies have failed (e.g., an indication for
319 second-line use), consideration should be given as to whether it is necessary to specify the name
320 of the drug(s) or drug class(es) the patients are to have initially received or instead to word the
321 indication more broadly (e.g., for use in previously treated patients).

- 322
323 b. Adjunctive or concomitant therapy or therapeutic modalities to use before
324 initiating drug therapy, such as diet or exercise or another drug

325
326 If the drug is approved for use only in conjunction with a primary mode of therapy (e.g., diet,
327 surgery, behavior changes, or another drug), “[t]his section must include...a statement that the
328 drug is indicated as an adjunct to that mode of therapy” (§ 201.57(c)(2)(i)(A)). For example:

- 329
330 • DRUG-X is indicated in adults for the treatment of high-grade malignant
331 glioma as an adjunct to surgery and radiation.

332
333 For drugs approved for use as adjunctive therapy, consideration should be given as to whether it
334 is necessary to specify the name of the drug(s) or drug class(es) the patients are to receive
335 concomitantly or instead to word the indication more broadly (e.g., as adjunctive therapy or as
336 part of a combination regimen).

- 337
338 c. Specific tests needed to select patients in whom to use the drug

339
340 If specific tests are necessary for selection or monitoring of patients who need the drug, “[t]his
341 section must include...the identity of such tests” (§ 201.57(c)(2)(i)(C)).¹⁸ For example:

- 342
343 • DRUG-X is indicated for the treatment of adult patients with metastatic
344 non-small cell lung cancer whose tumors are anaplastic lymphoma kinase
345 (ALK)-positive as detected by an FDA-approved test.

346
347 In general, information on tests used for monitoring appears in other labeling sections (e.g.,
348 DOSAGE AND ADMINISTRATION or WARNINGS AND PRECAUTIONS).¹⁹

349

¹⁸ When appropriate, the labeling should identify the type of FDA-approved or cleared in vitro companion diagnostic device with which the product is approved, rather than a particular manufacturer’s device. See the guidance for industry and FDA staff *In Vitro Companion Diagnostic Devices*.

¹⁹ See the following two guidances for industry: (1) *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* and (2) *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format*.

350 **B. Limitations of Use**

351
352 *Limitations of use* are presented separately from the indication within the INDICATIONS AND
353 USAGE section (see section III.D.2). A limitation of use is included when there is reasonable
354 concern or uncertainty among FDA’s expert reviewers, who are qualified by scientific training
355 and experience, about a drug’s risk-benefit profile. Limitations of use should be distinguished
356 from contraindications. A contraindication “must describe any situations in which the drug
357 should not be used because the risk of use (e.g., certain potentially fatal adverse reactions)
358 clearly outweighs any possible therapeutic benefit” (§ 201.57(c)(5)). However, there are cases in
359 which the evidence falls short of requiring a contraindication, but suggests that use of the drug
360 may be inadvisable. There are also cases in which there is sufficient uncertainty about the drug’s
361 benefits in certain clinical situations to suggest that the drug should generally not be used in
362 those settings. In these cases, a limitation of use may be appropriate. To avoid redundancy
363 within the labeling, contraindications should not be restated as limitations of use in the
364 INDICATIONS AND USAGE section.

365
366 Limitations of use should be included in the INDICATIONS AND USAGE section only when
367 the awareness of such information is important for practitioners to ensure the safe and effective
368 use of the drug. In most cases, limitations of use will identify a particular patient population in
369 which a drug should generally not be used. If evidence is available to support the safety and
370 effectiveness of the drug only in selected subgroups of the larger population, the INDICATIONS
371 AND USAGE section “must include... a succinct description of the limitations of usefulness of
372 the drug and any uncertainty about anticipated clinical benefits, with reference to the ‘Clinical
373 Studies’ section for a discussion of the available evidence” (§ 201.57(c)(2)(i)(B)). Such
374 information would be appropriate to include as a separate limitation of use — rather than
375 narrowing the language of the indication itself — when needed to inform practitioners that there
376 is a reasonable concern or uncertainty about the drug’s safety or effectiveness outside the
377 specific population for which the drug is approved.

378
379 In contrast, information that essentially narrows or further defines a drug’s approved indication
380 and is used to direct appropriate therapy (e.g., identifying particular subsets of the population for
381 whom the drug is approved, drugs to be used only after other drug therapies have failed, or
382 specific tests needed to identify patients to be treated) should be incorporated directly into the
383 indication whenever possible (see section III.A.2). This information should not be presented as a
384 separate limitation of use. Whereas a limitation of use most often will be included to identify a
385 patient population in which the drug should generally *not* be used (i.e., discouraging its use),
386 information that specifies the patient population in which the drug *should* be used (i.e.,
387 encouraging its use) should, wherever possible, be incorporated in the indication itself. For
388 example, if a drug should be used only after failure of or as an adjunct to another drug or
389 treatment modality, the indication should include this information rather than having it presented
390 separately as a limitation of use.

391
392 Although there are invariably areas of uncertainty about a drug’s effectiveness, not all drugs will
393 include limitations of use in the INDICATIONS AND USAGE section. Information considered
394 for a limitation of use should be evaluated to decide if it may be better suited to another section
395 of the labeling (e.g., WARNINGS AND PRECAUTIONS, USE IN SPECIFIC POPULATIONS,

396 CLINICAL STUDIES). For example, although there may be circumstances in which a
397 limitation of use will be further described in (and cross-referenced to) a subsection in the
398 WARNINGS AND PRECAUTIONS section, most warnings and precautions will typically not
399 be repeated as limitations of use. Only information that provides a clearer understanding of the
400 scope of the approved indication to facilitate safe and effective prescribing decisions should be
401 included as a limitation of use. Moreover, an absence of data in a particular population subset
402 should generally not appear as a limitation of use unless there is reasonable concern about the
403 drug’s safety or effectiveness in that group.

404

405 *1. Situations in Which Limitations of Use Would Be Appropriate*

406

407 The following are examples of situations in which it may be appropriate to include a separate
408 limitation of use within the INDICATIONS AND USAGE section:

409

- 410 a. Drugs for which there is reasonable concern or uncertainty about effectiveness
411 or safety in a certain clinical situation

412

413 As recommended in section II.A.2, the approved age group(s) should be included in an
414 indication. If there is a concern or uncertainty about safety or effectiveness in a population
415 outside the approved age group (e.g., younger patients), a limitation of use should be included
416 about that population. The inclusion of a limitation of use will differentiate between (1) a
417 circumstance in which use of the drug in a certain population outside of the approved population
418 raises a reasonable concern or uncertainty about safety or effectiveness and (2) a circumstance in
419 which an indication is simply directed to a certain group (e.g., patients within a particular age
420 range). The concern that warranted the limitation of use should typically be described elsewhere
421 in labeling (e.g., WARNINGS AND PRECAUTIONS and USE IN SPECIFIC POPULATIONS
422 sections), with a cross-reference in the limitation of use to the section of labeling where this
423 detailed information can be found. For example:

424

- 425 • DRUG-X is indicated for the treatment of hypertension in adults and
426 pediatric patients 1 year of age and older.

427

428 Limitations of Use

429

430 In patients younger than one year of age, DRUG-X can adversely affect
431 kidney development [*see Warnings and Precautions (5.X) and Use in
432 Specific Populations (8.4)*]

432

433 The governing regulation states that “[i]f there is a common belief that a drug may be effective
434 for a certain use or if there is a common use of the drug for a condition, but the preponderance of
435 evidence related to the use or condition shows that the drug is ineffective or that the therapeutic
436 benefits do not generally outweigh its risks, FDA may require that [the INDICATIONS AND
437 USAGE] section state that there is a lack of evidence that the drug is effective or safe for that use
438 or condition” (§ 201.57(c)(2)(ii)). A limitation of use may be of particular importance in these
439 circumstances if proven alternative therapies exist for the condition in question. For example:

440

- 441 • DRUG-X is indicated in adults for the acute treatment of migraine
442 headache with or without aura.

443
444 Limitations of Use

445 Multiple clinical trials failed to establish the effectiveness of DRUG-X for
446 the prophylaxis of migraine headaches [*see Clinical Studies (14.X)*].

- 447
448 b. Drugs approved without evidence of benefits known to occur with other drugs
449 in the same class

450
451 If a drug is approved without having demonstrated a particular benefit that has been
452 demonstrated with other drugs in the same pharmacologic or therapeutic class, it may be
453 important to convey the differences among products under a “Limitations of Use” heading in the
454 INDICATIONS AND USAGE section. For example, the INDICATIONS AND USAGE section
455 for a new HMG-CoA reductase inhibitor that is approved based on its serum lipid-lowering
456 effects (without evidence of a beneficial effect on cardiovascular morbidity and mortality) would
457 typically be presented as follows:

- 458
459 • DRUG-X is indicated as an adjunctive therapy to diet to reduce elevated
460 total cholesterol, LDL cholesterol, apolipoprotein B, and triglycerides and
461 to increase HDL cholesterol in adult patients with primary hyperlipidemia
462 or mixed lipidemia.

463
464 Limitations of Use

465 The effect of DRUG-X on cardiovascular morbidity and mortality has not
466 been determined.

- 467
468 c. Drugs with dose, duration, or long-term use considerations

469
470 If information on limitations of use or uncertainty about anticipated benefits is relevant to the
471 recommended dosing intervals, to appropriate treatment duration when treatment should be
472 limited, or to any dosage modification, the INDICATIONS AND USAGE section “must
473 include...a concise description of the information, with a reference to the more detailed
474 information in the ‘Dosage and Administration’ section” (§ 201.57(c)(2)(i)(D)). Under these
475 circumstances, information about important dose or duration considerations, such as how long a
476 drug can safely be used or uncertainty about the risks and benefits of treatment beyond a certain
477 period (e.g., long-term cumulative toxicity), should be included as a limitation of use. For
478 example:

- 479
480 • DRUG-X is indicated for the management of elevated plasma uric acid
481 levels in adult patients with tumor lysis syndrome.

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Limitations of Use

The activity of DRUG-X may be neutralized by the development of anti-drug antibodies if more than a single course of treatment is administered [see *Dosage and Administration (2.X) and Warnings and Precautions (5.X)*].

It is generally not necessary to limit duration of use in the INDICATIONS AND USAGE section unless such a limited duration is essential to ensure the safe and effective use of the drug. If clinical trials evaluated the effectiveness of a drug for a chronic condition only in short-term trials of sufficient duration to support such an approval (e.g., drugs for major depressive disorder or hypertension), but the drug is indicated for long-term use due to the chronic nature of the condition and because there is no known or anticipated safety or efficacy concern from continued use, a description of the duration of use from the clinical trials or information about the lack of longer term data generally should not be included in the INDICATIONS AND USAGE section. Information on the length of the clinical trials should instead be discussed in detail in the CLINICAL STUDIES section of the labeling.

If there are specific conditions that should be met before the drug is used on a long-term basis (e.g., demonstration of responsiveness to the drug after short-term use in an individual patient), the INDICATIONS AND USAGE section “must include...a statement of the conditions; or if the indications for long term use are different from those for short term use, a statement of the specific indications for each use” (§ 201.57(c)(2)(i)(F)). For drugs with these characteristics, a limitation of use may be used to address such issues. For example:

- DRUG-X is indicated for the treatment of severe spasticity in adult patients with spinal cord injury, brain injury, or multiple sclerosis.

Limitations of Use

Prior to implantation of a device for chronic intrathecal infusion of DRUG-X, confirm a positive clinical response to DRUG-X in a screening phase [see *Dosage and Administration (2.X)*].

2. *Situations in Which Limitations of Use Generally Would **Not** Be Appropriate*

Limitations of use generally would **not** be appropriate in the following situations:

- a. To restate information already included in the indication

For example, if an indication is clearly worded as being approved for use in combination with another drug, there is no need for a limitation of use stating that the subject drug should be used only in combination and not as monotherapy.

526 b. To address the absence of data in populations in which the drug was not
527 studied
528

529 For example, if an oncology drug was studied in and is indicated for use in patients with a cancer
530 of a specific mutation, there should not be a limitation of use about the absence of data in
531 patients with typical (wild-type) forms, unless there is reasonable concern about the drug’s safety
532 or effectiveness in such patients. Likewise, if a drug is approved to reduce the risk of rejection in
533 patients receiving a heart transplant, there should not be a limitation of use about the lack of data
534 on use in lung transplants. Similarly, if a vaccine is approved for use in children 12 months
535 through 12 years of age, there should not be a limitation of use about the absence of data in other
536 age groups.

537
538 **C. Other Considerations for Writing the INDICATIONS AND USAGE Section**
539

540 *1. Identification of Outcomes, Endpoints, and Benefit(s) the Drug Conveys*
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542 The approved indication will generally convey the benefit of the treatment (i.e., the disease,
543 condition, manifestation, or symptoms of the disease or condition being treated, prevented,
544 mitigated, cured, or diagnosed), and it is usually not necessary to fully describe the specific way
545 benefit was measured in clinical trials (i.e., identifying outcomes or endpoints) when the
546 treatment affects a broad range of manifestations of the disease (e.g., an indication for the
547 symptoms of allergic rhinitis). In some cases, however, a broad disease indication may not be
548 appropriate because, for example, the drug may affect only certain signs, symptoms, or
549 manifestations of the disease (see section III). An indication identifying an outcome or endpoint
550 may be considered, for example, when the drug’s effect on the overall disease is not well
551 understood, when different drugs have different effects on various manifestations of the diseases,
552 when clinical trials evaluated only one or some of the manifestations of the disease, or when the
553 endpoints are different from typical effectiveness measures. For example:

- 554
555 • DRUG-X is indicated to improve walking in adult patients with multiple sclerosis.

556
557 For certain other conditions, the drug’s indication may be to reduce the risk of significant
558 morbidity and mortality, which describes the demonstrated benefit more accurately than would a
559 more broadly written indication indicating the product simply as a treatment for the condition
560 itself. In such cases, the specific endpoint(s) for which the drug has demonstrated benefits
561 should be incorporated into the indication. For example:

- 562
563 • DRUG-X is indicated to reduce the risk of nonfatal myocardial infarction, fatal
564 and nonfatal stroke, and revascularization procedures in adult patients with
565 clinically evident coronary heart disease.

566
567 The CLINICAL STUDIES section of labeling “must discuss those studies that facilitate an
568 understanding of how to use the drug safely and effectively” (§ 201.57(c)(15)). The information
569 presented in that section ordinarily includes, among other things, a description of the study
570 population, endpoints, and results. For example, if an indication were written for an overall
571 effect on a composite endpoint, the details on the endpoints studied and results (e.g., which

572 component of a composite endpoint drove the overall combined finding) would be discussed in
573 detail in the CLINICAL STUDIES section. Additionally, if only one component of a composite
574 primary endpoint was affected and indicating the drug for the composite would misrepresent the
575 true result, an indication for the single component can be considered, with the explanation of the
576 study results summarized in the CLINICAL STUDIES section.

577

578 2. *Accelerated Approval*

579

580 If a drug is approved for an indication based on an effect on a surrogate endpoint or an
581 intermediate clinical endpoint under section 506(c) of the Federal Food, Drug, and Cosmetic Act
582 (FD&C Act) (21 U.S.C. 356(c)) and 21 CFR 314.510 or 601.41 (i.e., accelerated approval), the
583 INDICATIONS AND USAGE section “must include...a succinct description of the limitations
584 of usefulness of the drug and any uncertainty about anticipated clinical benefits, with a reference
585 to the Clinical Studies section for a discussion of the available evidence”
586 (§ 201.57(c)(2)(i)(B)).²⁰

587

588 3. *Required or Recommended Language*

589

590 Under governing statutory and regulatory provisions, certain products have required or
591 recommended language for the INDICATIONS AND USAGE section. For example:

592

- 593 • Labeling for systemic antibacterial drug products must include a specific
594 statement in the INDICATIONS AND USAGE section about strategies for
595 reducing the development of drug-resistant bacteria and maintaining the
596 effectiveness of the subject drug and other antibacterial drugs (21
597 CFR 201.24(b)).
- 598
- 599 • Section 505(u)(2)(B) of the FD&C Act (21 U.S.C. 355(u)(2)(B)) requires that
600 labeling for certain products containing a single enantiomer of a previously
601 approved racemic drug include a statement that the non-racemic product is not
602 approved, and has not been shown to be safe and effective, for any condition of
603 use of the previously approved racemic drug. For such products approved under
604 505(u), this information should be presented as a limitation of use.
- 605
- 606 • Other FDA guidances (e.g., clinical/medical guidances) recommend specific
607 wording for the INDICATIONS AND USAGE section for certain indications.²¹
- 608

²⁰ See the draft guidance for industry *Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway*. When final, this guidance will represent FDA’s current thinking on this topic.

²¹ Additional labeling guidances are available on the FDA Drugs guidance web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

609 4. Preferred Wording and Wording Generally To Avoid²²

610
611 Consistent with this guidance and the regulatory framework, as a general matter, care should be
612 taken when considering use of the following terms and phrases:

613
614 a. “Reduce the risk” versus “prevent”

615
616 If the indication for a drug is to reduce the risk of the occurrence of a particular clinical outcome,
617 phrases such as “reduce the risk of” or “reduce the incidence of” should be considered rather
618 than using “prevent” in the indication. The use of a term such as *prevent* may imply a guarantee
619 of success that is not supported by the data. However, for certain indications, the use of terms
620 such as *prevent* (e.g., for preventive vaccines) or *prophylaxis* (e.g., drugs for post-exposure
621 prophylaxis) in the indication may be appropriate because, in a given context, these terms are
622 well established and understood by the clinical community.

623
624 b. “Only”

625
626 The INDICATIONS AND USAGE section should be worded clearly to convey the approved use
627 of the drug, making inclusion of the word “only” unnecessary (i.e., the indication generally
628 should *not* state “DRUG-X is indicated only for...”).

629
630 c. “Also indicated”

631
632 When a new indication is added to the INDICATIONS AND USAGE section, the phrase “is also
633 indicated” generally should *not* be used because it may imply that the new indication is less
634 important than the existing indication(s).

635
636 d. Product identification in the indication

637
638 The indication should include the proprietary name (or trade name). If the product does not have
639 a proprietary or trade name, the indication should include the nonproprietary name (i.e.,
640 established name for a drug product or proper name for a biological product).

641
642 To avoid unnecessary clutter and to enhance clarity, other information (such as the non-
643 proprietary name, dosage form, route of administration) generally should not be included in the
644 indication. The established pharmacologic class appears with the indication only in Highlights
645 (§ 201.57(a)(6)).

646
647 **D. Formatting the INDICATIONS AND USAGE Section**

648
649 1. *Format for Multiple Indications*

650
651 When a drug is approved for more than one indication, the format of the INDICATIONS AND
652 USAGE section should be carefully considered. For some drugs, it may be preferable to assign a
653 subsection to each indication (e.g., 1.1 Disease-A, 1.2 Disease-B), but for others, it may be

²² See generally 21 CFR 201.56.

654 preferable to present distinct indications using only bullets (e.g., “DRUG-X is indicated for:”
655 followed by a bulleted list) immediately under the main section heading or within a subsection.
656

657 2. *Format for Limitations of Use*
658

659 Limitations of use are presented separately from the indication within the INDICATIONS AND
660 USAGE section, under the heading *Limitations of Use* and not usually under a separate
661 numbered subsection. If, however, a drug has multiple indications and the limitations of use
662 apply to all of them, it may be preferable to use a separate numbered subsection for *Limitations*
663 *of Use* within the section. The INDICATIONS AND USAGE section should be formatted to
664 clearly show if the limitations apply to all or to only some of the indications.
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Attachment 7



GOAL

4

COMMUNICATION AND PUBLIC EDUCATION

The board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

- 4.1** Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.
- 4.2** Identify and use additional resources for public and licensee outreach services to implement the communication plan.
- 4.3** Establish a process to collect e-mail addresses and mobile numbers for text messaging from all licensees for better ability to improve communication.
- 4.4** Provide implementation guidance on newly enacted changes to Pharmacy Law by publishing summaries and explaining implementation tactics.
- 4.5** Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.
- 4.6** Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.
- 4.7** Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.
- 4.8** Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.