



## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

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

### 1. Call to Order and Establishment of Quorum

### 2. Public Comment for Items Not on the Agenda; Matters for Future Meetings

*The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to place the matter on a future meeting agenda. [(Government Code sections 11125 & 11125.7(a))]*

### 3. Approval of the January 31, 2018, Committee Meeting Minutes

A copy of the minutes is in **Attachment 1**.

### 4. Discussion and Consideration of a Presentation by the Chapman University School of Pharmacy Group Regarding a Warning Label on Prescription Containers for Chemotherapy Medications

#### 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. An article about the group's research and proposal was published in the October 2017 issue of The Script.

At the September 2017 committee meeting, Chapman pharmacy professors presented early findings of a survey of health care professionals on the use and handling of oral chemotherapy drugs. The professors also said they were preparing a similar survey for patients. The committee thanked them for the group's work and urged them to provide more findings when the surveys were completed.

#### At this Meeting

The Chapman group is expected to present survey findings requested by the committee and additional data related to the use and handling of oral chemotherapy medications.

Following the presentation, the committee may wish to discuss and consider what action, if any, the board might discuss and consider regarding a warning label on prescription containers for chemotherapy medications. Possible options include:

- A mandate – This would likely be a new board regulation requiring pharmacists to put a new warning label on prescription containers.
- A policy statement – This could be a formal statement by the board encouraging pharmacists to put a warning label on prescription containers and to educate patients about appropriate handling and disposal of such drugs.
- Possible education materials for the public.

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

Background

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

The committee presented the final billboard design and message at the February 2018 board meeting. A copy of the billboard is in **Attachment 2**.

Update

Staff has been working with Outfront Media and DCA to draft a no-cost contract for the five billboards. The process has required a lot of time, paperwork and communications among board staff, DCA staff and Outfront. Staff has worked to expedite the contract process and invited DCA staff to explain the process to the committee.

In the meantime, staff has updated the board’s consumer materials on prescription drug abuse. The board’s [prescription drug abuse webpage](#) has been redesigned to include links to information about prevention, education and treatment. Visitors also can view the board’s video public service announcement about prescription drug abuse.

In addition, staff has launched an online search tool for prescription drug take-back locations. More details and a demonstration of the online search tool will be presented under a separate agenda item at this committee meeting.

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

Background

In June 2017, the board secured regulations for pharmacies and clinics to establish prescription drug take-back services, including collection receptacles and mail-back envelopes. The board recognized that providing opportunities for consumers to dispose of unused medications is an effective way to prevent prescription drug abuse.

At its July 2017 meeting, 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.

#### At this Meeting

Staff will provide a brief demonstration of the online search tool for drug collection receptacles. As of Sept. 25, 233 receptacle locations were registered with the board.

Staff also is researching additional resources for drug take-back services for consumers. The Department of Public Health has notified staff of \$3 million available to fund grants to pharmacies for drug take-back services. The first grants could be awarded as soon as October 2018.

In addition, the Governor is expected to sign SB 212, which would create a statewide take-back program for sharps and medications. SB 212 essentially would require manufacturers or distributors of covered drugs or sharps to form stewardship organizations to operate take-back programs. The bill would require each stewardship organization to pay all administrative and operational costs for take-back programs. SB 212 also requires CalRecycle to promulgate regulations to implement the bill by Jan. 1, 2021.

A copy of SB 212 is in **Attachment 3**.

### **7. Update on the Development of a 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. There are several ways consumers can receive naloxone for themselves or others who are at risk of opioid overdose, including:

- Prescribers – Patients who are prescribed opioids by a doctor or other prescriber can ask to also receive a prescription for naloxone.
- Pharmacists – California law authorizes pharmacists to independently furnish naloxone to patients pursuant to a protocol adopted by the board.
- Schools – [Business and Professions Code section 4119.8](#) authorizes pharmacies to furnish naloxone to school districts for use at schools.
- Community agencies – The California Department of Public Health has issued a standing order for naloxone. This order enables county health departments, treatment centers and needle exchange programs to make naloxone available to patients and clients at risk of overdose.
- Law enforcement – [AB 2256](#), a bill authorizing pharmacies to furnish naloxone to law enforcement agencies, was signed by the Governor in September 2018.

Pharmacists who wish to furnish naloxone without a prescription must comply with the requirements of the board's protocol, which is established 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.

At the February 2018 board meeting, 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.

#### Update

Staff has been working with the authors of the course materials and with DCA's SOLID training unit to develop video webinar. SOLID is expected to complete and deliver the video webinar to be posted on the board's website in October.

### **8. Discussion and Consideration of Proposal to Establish a Twitter Account for the Board of Pharmacy**

#### Background

The board's 2017-2021 Strategic Plan calls for the board to "identify and use additional resources for public and licensee outreach services" to implement a communication plan. The board currently has many channels for communicating primarily with licensees – including a website, subscriber alerts, The Script, the Ask a Pharmacist program, site inspections, CE training forums and online webinars.

Staff is proposing using the social media platform Twitter as a new resource for outreach to the public as well as licensees. Besides communicating information directly to consumers, having a presence on Twitter would increase public awareness and appreciation for the board's mission and activities.

#### At this Meeting

Staff will give a brief presentation on the use of Twitter as a communication channel for the public, including consumers. After the presentation, the committee is invited to discuss and consider the proposal.

Should the committee approve the proposal, the following language could be used in a recommendation to the board:

**Recommendation:** The committee recommends 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.

### **9. Discussion on Development of Frequently Asked Questions Relating to Inventory Reconciliation Reports of Controlled Substances (California Code of Regulations, title 16, section 1715.65)**

#### Background

In January 2018, the Office of Administrative Law approved a major board regulation intended to help pharmacies and clinics prevent drug losses and identify any losses early. Among other things, the regulation requires pharmacies and clinics to perform a periodic inventory reconciliation for all controlled substances, as well as a physical hand count of all Schedule II drugs every three months. The regulation – [California Code of Regulations, title](#)

[16, section 1715.65](#) – took effect April 1, 2018.

### Discussion

The new regulation has prompted many questions from pharmacies and clinics about how to comply with the inventory reconciliation requirements. At this meeting, staff is updating the committee on steps being taken to help licensees understand the requirements.

Staff compiled and posted a list of [frequently asked questions \(FAQs\)](#) and answers on the board's website next to the regulation text. The FAQs also were updated and published in the [July 2018 issue](#) of The Script. A copy of the newsletter article is in **Attachment 4**.

Since then, board inspectors and staff have continued working together to educate licensees about the regulation. A follow-up article with more questions and answers is planned for the next Script.

In addition, staff gave a presentation on the new regulation and FAQs at the September 2018 Enforcement and Compounding Committee meeting. Staff also provided training on the regulation at a board-sponsored CE forum on Sept. 22 in Buena Park.

## **10. Discussion and Consideration of Granting CE Credit for Reading The Script**

### Background

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

At the February 2018 board meeting, the board directed the committee to pursue options for awarding CE for The Script that would be a way for pharmacists to earn the two hours of board-provided CE in law and ethics every renewal cycle. The board also asked staff to research ways to implement the CE program while keeping costs and required staff time to a minimum.

### At This Meeting

Staff is presenting three options for the committee to consider for awarding CE for The Script. Staff would work with DCA on the mechanics for implementation.

The options are:

- 1. Require pharmacists to self-certify reading The Script.** With this option, participants 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.** With this option, participants could click on a link that would open a quiz of multiple-

choice and true-false questions. This option would require staff time to prepare questions and answers for articles for each newsletter. In addition, newsletter materials require legal review before publication. **Estimated staff time to process each CE unit: one minute.**

- 3. Require pharmacists to complete learning objectives after reading The Script.** With this option, participants could click on a link that would open a box where they would write a brief description of what they learned from reading the newsletter. This option would require more technical capabilities and staff time to review participants' responses. **Estimated staff time to process each CE unit: five to 15 minutes.**

#### Staff Recommendation

Staff expects there will be a high demand among pharmacists seeking CE units for reading the newsletter. If only half of licensed pharmacists choose this option, that would generate claims for more than 20,000 CE units per newsletter.

For this reason, staff recommends option 1 for awarding CE for reading The Script. This option would be the most straightforward to implement and would require the least staff time to process each CE unit.

Should the committee agree, the following language could be used in a recommendation to the board:

**Recommendation:** The committee recommends the board approve an option allowing pharmacists to self-certify reading The Script to earn one hour of CE credit per newsletter, up to a maximum of two credits, as fulfillment of the two units of CE required to be earned from completion of board-provided CE to renew a pharmacist license.

#### **11. Discussion and Consideration of FDA Draft 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, “[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. The guidance also addresses circumstances where FDA regulations require that other information besides identifying the disease or condition must be included in the “Indications and Usage” section.

This agenda item is for the committee's information; no action is required. A copy of the FDA guidance document is in **Attachment 5**.

## **12. Discussion and Consideration of Strategic Goals for the Communication and Public Education Committee**

In 2016, the board finalized its current strategic plan, [Strategic Plan 2017-2021](#). Staff recommends the committee discuss its strategic goals for the current fiscal year and the remainder of the plan period. A copy of the Communication and Public Education section of the strategic plan is in **Attachment 6**.

Below are the current Communication and Public Education goals and a status report for each goal. The committee may wish to discuss specific actions or projects to accomplish each goal.

### **4.1. Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.**

Status: The committee approved a communication plan at its September 2016 meeting in accordance with the board's Strategic Plan goal to "(educate) consumers, licensees and stakeholders about the practice and regulation of the profession."

### **4.2. Identify and use additional resources for public and licensee outreach services to implement the communication plan.**

Status: The board reinstated the Ask an Inspector program for licensees. The board also sponsors CE training events throughout the state and has created webinars for law and ethics CE and naloxone training. In addition, staff is proposing the use of social media to expand communications with the general public.

### **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.**

Status: The board has expanded its email notification program. In addition to facilities and pharmacists, the board now also requires pharmacy technicians, intern pharmacists and designated representatives to register email addresses to receive official notifications.

### **4.4. Provide implementation guidance on newly enacted changes to Pharmacy Law by publishing summaries and explaining implementation tactics.**

Status: The board is providing extensive guidance on the inventory reconciliation regulation through FAQs, newsletter articles and live CE training forums. The board also has published on its website FAQs about compounding, drug take-back programs and SB 493.

### **4.5. Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.**

Status: Board inspectors are working to meet this goal by adjusting schedules and workloads to increase the frequency of routine inspections.

### **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.**

Status: The board has developed an online search tool to help consumers find local pharmacies that offer drug take-back services.

**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.**

Status: The board has updated its “Counterfeit Prescription Drugs” brochure, which warns consumers about the dangers of buying drugs online.

**4.8. Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.**

Status: The board is planning a campaign about prescription drug abuse with a public service message on five billboards donated by Outfront Media. The Board also has sponsored periodic CE training forums on prescription drug abuse throughout the state.

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

**a. The Script**

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

**b. News Media**

The board’s executive officer and public information officer participated in interviews or provided background information 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.

**c. Public Outreach Activities**

- 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
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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.

#### **14. Review and Discussion of News or Journal Articles**

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

##### [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

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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**.

**15. Future Meeting Dates**

A list of future committee meeting dates will be distributed at this meeting.

# **Attachment 1**



**COMMUNICATION AND PUBLIC EDUCATION COMMITTEE  
MEETING MINUTES**

**Date:** January 31, 2018

**Location:** Department of Consumer Affairs  
DCA Headquarters Building  
1625 N. Market Blvd., 1<sup>st</sup> Floor Hearing Room  
Sacramento, CA 95834

**Committee Members Present:** Ricardo Sanchez, Public Member, Chairperson  
Debbie Veale, Licensee Member, Vice Chairperson  
Victor Law, Licensee Member

**Committee Members Not Present:** Ryan Brooks, Public Member  
Amjad Khan, Public Member

**Staff Present:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Kelsey Pruden, DCA Staff Counsel  
Bob Dávila, Public Information Officer

**1. Call to Order and Establishment of Quorum**

Chairperson Sanchez called the meeting to order at 9:09 a.m. Roll call was taken, and a quorum was established.

**2. Public Comment for Items Not on the Agenda, Matters for Future Meetings**

There was no public comment.

**3. Presentation by Ramón Castellblanch, Ph.D., Regarding Prescription Drug Overdose Prevention and Corresponding Responsibility**

Former board member Ramón Castellblanch presented information about the growing number of opioid deaths from overdoses and the effectiveness of naloxone in reversing

overdoses. He said pharmacy board websites can be valuable educational tools for stopping overdoses and offered a sample from the Kentucky Board of Pharmacy website. The Kentucky website features a prominent box on the homepage that links directly to a separate website dedicated to opioid overdose prevention.

Dr. Castellblanch also said he found confusion among California pharmacists about what corresponding responsibility is, about how to use CURES and about calculating morphine equivalents. He said some states require CE about the opioid epidemic for pharmacists, including Iowa, Florida and Oregon. He said more needs to be done to educate pharmacists about the opioid epidemic.

Committee members thanked Dr. Castellblanch for his presentation. Ms. Herold noted the board has provided training on naloxone and corresponding responsibility to about 700 pharmacists at CE seminars cosponsored with the DEA around the state. The committee discussed the importance of educating pharmacists about naloxone and “red flags.” Members directed staff to explore ways to make information about naloxone and “red flags” more visible on the website, including a main button on the homepage that links directly to the information on the website.

The committee and members of the public also discussed the importance of getting pharmacists more comfortable and proactive in speaking to patients, parents and the public about naloxone and stopping opioid overdoses. The discussion also included comments about patient resistance to getting naloxone because of perceived stigma; issues of insurance coverage and reimbursement for naloxone; and possible CE credit for training on how to host a drug take-back collection bin.

#### **4. Discussion and Consideration of a Proposal for a Public Service Billboard Message and Related Communications Materials on Drug Abuse**

Chairperson Sanchez reminded the committee at the November 2017 board meeting, the board considered several possible messages presented by the committee for a billboard about drug abuse prevention. The board directed Chairperson Sanchez and Ms. Herold to make the final selection and to work on the project with Outfront Media.

Chairperson Sanchez reported that he and Ms. Herold chose “Use, Don’t Abuse” for the billboard message. He said they also selected a final overall design for the billboard – including the message, artwork and the Board of Pharmacy logo and website.

Chairperson Sanchez said prescription drug abuse information on the board’s website is being revamped with a fresh look and resources. He said the billboard would be featured on the homepage and would serve as a link to a separate webpage dedicated to information about drug abuse and where to dispose of unused medications.

Chairperson Sanchez reported the billboard design is being prepared for submission to Outfront Media. He said staff would have the new webpage up and running before the billboards are erected, with a goal of completion this spring.

The committee requested that information about drug take-back collection sites from multiple resources be centralized into a single locator map. Members emphasized keeping the list of resources simple and easy for consumers to use while also expanding the scope beyond prescription drugs to include other forms of substance abuse. The committee directed staff to keep moving forward with the project and to provide an update on progress at the next meeting.

Heidi Sanborn of the California Public Stewardship Council (CPSC) urged the committee not to launch the webpage without a locator map for collection bins. Otherwise, she said, consumers might dispose of unwanted drugs by simply flushing them.

**5. Discussion and Consideration of Possible Options for Consumer and Pharmacist Education Regarding Safe Medication Transitions for Patients upon Discharge from Health Care Facilities and Any Necessary Statutory or Regulatory Changes**

Chairperson Sanchez reminded the committee that at the July 2017 board meeting, the board directed the committee to discuss developing materials to educate consumers and pharmacists about the importance of having a patient medication history on hand when being admitted to a hospital. He said the board also asked staff to develop public outreach materials on this topic for the website.

The committee received printed information provided by Rita Shane, Pharm.D.; and a January 2018 [article](#) from U.S. News and World Report, “9 Strategies for Reducing Emergency Room Medication Errors.” Committee members discussed how to convey information about safe medication transitions to two distinct audiences – consumers and pharmacists.

The committee directed staff to explore ways to inform consumers about compiling and carrying a current medication inventory through various media, including the board’s website and the DCA’s blog, publications and social media accounts. The committee also staff to produce a *Script* article about the role of pharmacists in reducing medication errors during patient stays in hospitals. Members suggested sharing the *Script* article with other healing arts boards to share with their licensees.

The committee also discussed contacting pharmacy schools to ask if their curriculum includes training related to safe medication transitions. In addition, the committee also heard public comments from Dwight French of Wellspring Pharmacy in Oakland about how his pharmacy is starting a project with Alameda Health System to be a part of the hospital’s care transition program.

**6. Discussion and Consideration of Educational Materials Regarding Drug Take-Back Collection Receptacle and Providing Public Access to Such Information**

Chairperson Sanchez reminded the committee that at the July 2017 board meeting, the board directed the committee to develop consumer information on accessing drug take-back programs.

Staff reported that forms to report [installing or discontinuing a collection receptacle](#) and to report [tampering, damage or theft of a receptacle](#) are now posted on the board's website. Staff said the registration forms would be used to develop an online locator function for consumers to find drug take-back programs in their communities.

The committee asked how many registered collection receptacles were now in place. Staff reported that the forms were only recently made available online and that registrations had just started coming in. Ms. Herold said she received letters in January from some pharmacies reporting a total of about 200 collection bins statewide. She added that staff would remind pharmacies that the registration forms are now available in a *Script* article.

During public comments, Heid Sanborn of CPSC told the committee that her group would be happy to share its collection bin locations for inclusion on the board's website.

**7. Discussion and Consideration of Creating Webinar Course to Satisfy Education Requirement for Pharmacists to Furnish Naloxone**

Chairperson Sanchez reminded the committee that SB 493 authorized the board to address the problem of restricted public access to naloxone. The board responded with an emergency regulation in 2015 and a permanent regulation in 2016 establishing a protocol for pharmacists to furnish naloxone without a prescription.

Chairperson Sanchez also noted that last year, the board and the U.S. Drug Enforcement Administration (DEA) cohosted training sessions for pharmacists throughout the state that included one hour of CE credit to meet the education requirement of the naloxone protocol. The board and DEA are planning additional training sessions in 2018.

Staff requested the committee consider approval of a proposed webinar course to satisfy the one-hour CE requirement for furnishing naloxone. The course was developed by Talia Puzantian, Pharm.D., of Keck Graduate Institute School of Pharmacy and James J. Gasper, Pharm.D., California Department of Health Care Services.

During public comments, Dr. Gasper told the committee that the course material has been well received by pharmacists in several rural counties where it was presented in person. Ms. Herold said the webinar course would be an important part of the naloxone



materials on the board’s website. She added that the webinar would include a means for pharmacists to self-certify their participation and receive one hour of CE credit.

**Committee recommendation:** Create a webinar course using the materials presented by Dr. Gasper to satisfy the education requirements for pharmacists to furnish naloxone.

M/S: Veale/Law

Support: 4    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Khan				X
Law	X			
Sanchez	X			
Veale	X			

**8. Discussion and Consideration of UC Berkeley Study of the Availability of Contraception Prescribed by Pharmacists in California**

Chairperson Sanchez reminded the committee that SB 493 authorized California pharmacies to dispense hormonal contraception without a prescription. The board adopted a protocol for pharmacists to furnish self-administered hormonal contraception without a prescription in April 2016.

The committee received a UC Berkeley study published in the *Journal of the American Medical Association* in December 2017 that reported only 11 percent of California pharmacies are dispensing hormonal contraception to women without a prescription.

The committee took no action. During public comments, Dr. Gasper said issues surrounding wider availability of contraception are similar to the problems with naloxone, including reimbursement for the pharmacist’s services.

**9. Update and Discussion of FDA Proposal to Increase Consumer Protection from High-Risk Homeopathic Drugs**

Chairperson Sanchez informed the committee that in December 2017, the Food and Drug Administration (FDA) announced plans to change the way it regulates homeopathic drugs to a new approach based on potential risk to patients. The FDA said the new policy would focus on enforcement and regulation of homeopathic drugs that pose the greatest risk to patients.

Mr. Law noted that many homeopathic drugs are actually home remedies used in immigrant communities and imported from other countries. He said some of these

remedies may have ingredients that are actually harmful to patients, and they should be monitored and regulated by the FDA.

Ms. Herold noted that the FDA has begun issuing more recalls of homeopathic products. Ms. Veale noted that some pharmacy chains carry sections of homeopathic drugs and suggested sending out more subscriber alerts about recalls of these products.

The committee agreed to continue monitoring FDA activities in this area before considering whether board action is warranted.

The committee took a break at 10:50 a.m. and returned at 11:11 a.m.

**10. Discussion and Consideration of FDA Guidance, “Evaluating Drug Effects on the Ability to Operate a Motor Vehicle”**

Chairperson Sanchez reminded the committee that in April 2017, the board amended Title 16, California Code of Regulations [section 1744](#), to require pharmacists to include a written label on prescription drug containers warning the drug may impair a person’s ability to operate a vehicle or vessel. He noted the regulation identifies specific classes of drugs that may impair a person’s ability to drive a vehicle or vessel, and it requires pharmacists to add a warning to the container of any drug that, based on a pharmacist’s professional judgment, may impair a person’s ability to operate a vehicle or vessel.

The committee received a copy of an FDA guidance, “Evaluating Drug Effects on the Ability to Operate a Motor Vehicle,” issued in November 2017. The guidance notes the importance of preventing motor vehicle accidents that result from drug-impaired driving and the need for drug manufacturers to evaluate the effect of a drug on driving ability.

Committee members agreed that CCR section 1744 is comprehensive and needs no amendment.

**11. Discussion and Consideration of Journal of the American Pharmacists Association Article, “Enhancing the Educational Value of Direct-to-Consumer Advertising of Prescription Drugs”**

Chairperson Sanchez informed the committee that a study in the September/October 2017 issue of the Journal of American Pharmacists Association looked at how well consumers understand and retain information about the benefits and risks of a prescription drug that is conveyed in direct-to-consumer advertising (DTCA) by pharmaceutical companies.

Chairperson Sanchez said the study compared an original print DTCA with an ad modified by health literacy principles. The modified ad avoided medical terms, used

simple plain language, and was printed in at least 12-point font with information written at or below eighth-grade reading level.

Chairperson Sanchez reported that participants who viewed the modified ad understood and retained information about the drug's benefits and risks better than participants who viewed the original DTCA. He said the study suggested that risk information presented in the original DTCA was overwhelming for consumers.

Committee members agreed that the point of the study was beyond the committee's scope and took no action. Members noted that pharmaceutical advertising often is used by consumers to pressure doctors to prescribe medications that may not be needed.

## **12. Discussion and Consideration of Annual Report of the Research Advisory Panel of California**

Chairperson Sanchez informed the committee that California Health and Safety (HSC) Code sections 11480 and 11481 require research projects using certain Schedule I and Schedule II controlled substances as their main study drugs to be reviewed and authorized by the Research Advisory Panel of California. He noted the panel includes a member appointed by the Board of Pharmacy, Patrick R. Finley, Pharm.D.

Staff provided a copy of the advisory panel's recent annual report to the Legislature and the Governor. The committee took no action.

## **13. Discussion and Consideration of Granting Continuing Education Credit for Reading *The Script***

Chairperson Sanchez reminded the committee that at the November 2017 board meeting, members discussed the importance of *The Script* as a tool to communicate important information and training for licensees. He said members asked the committee to discuss and consider possible efforts to encourage readership, including possibly awarding CE credit for reading the newsletter.

The committee agreed that *Script* articles provide information worthy of CE credit. Ms. Veale noted that the board already awards CE for attending board and committee meetings. Members noted that the board requires two hours of CE on law and ethics. Ms. Veale and Ms. Herold said reading *The Script* could be applied to the requirement by awarding one CE credit for each issue read, up to a maximum of two hours.

Members discussed how to verify reading the newsletter. Ms. Herold said pharmacists could be required to self-certify reading *The Script*, just as they self-certify under penalty of perjury earning CE for renewing their licenses. Mr. Law and Ms. Veale suggested requiring pharmacists to pass a quiz included with *The Script*. Ms. Herold noted that,

depending on how the test is developed, the process could require additional staff time to accept the test, check the result and process the CE certificate.

The committee directed staff to report back on the feasibility of attaching a quiz to the newsletter that would require a participant to answer correctly before moving to the next question.

During public comment, Paige Talley said her members support awarding CE for reading *The Script* because it is hard for them to attend board and committee meetings. Danny Martinez of the California Pharmacists Association said CPhA would not oppose the idea but believes a quiz on the newsletter should be required to earn CE credit.

**Committee recommendation:** Direct the Communication and Public Education Committee to pursue awarding CE credit for reading *The Script* that would apply to the board requirement to earn two hours of CE in law and ethics.

#### **14. Update and Discussion of Communication and Public Education Activities by Board Staff**

##### **a. Communication Plan for Consumers and Licensees**

The committee received an update on staff activities since the previous committee meeting.

##### **b. The Script**

Staff reported that publication is imminent. The issue will highlight new pharmacy laws for 2018.

##### **c. News Media**

The committee received a list of recent media interviews and information requests provided by Ms. Herold and Mr. Dávila.

##### **d. Public Outreach**

The committee received a list of recent public outreach activities by staff.

#### **15. Review and Discussion of News or Journal Articles**

The committee received a list summarizing several recent news articles about pharmacy issues.

## **16. Future Meeting Dates**

Chairperson Sanchez reminded the committee of future meetings scheduled for 2018:

- April 25, 2018.
- July 11, 2018.
- Oct. 11, 2018.

The meeting adjourned at 11:41 am.

# **Attachment 2**

# Use, Don't Abuse

Safely Dispose of Unused Medications  
Stop Prescription Drug Abuse



For more information visit: [www.pharmacy.ca.gov](http://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

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*Governor*

# **Attachment 4**

# 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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### 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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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.

See [Inventory reconciliation FAQs](#), Page 10

## 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

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# 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:*

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*<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

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**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 Industry<sup>1</sup>**  
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 products<sup>2</sup> (21 CFR 201.57(c)(2)).<sup>3</sup>  
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 limitations of use in the INDICATIONS AND USAGE section  
28  
29  
30  
31

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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>.

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- 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.

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### **A. Scope of the Indication(s)**

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

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

#### *1. Scope of an Indication Relative to the Population Studied*

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

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

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<sup>4</sup> 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).

<sup>5</sup> 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*.

<sup>6</sup> See generally 21 U.S.C 355(d).

<sup>7</sup> See 21 CFR 312.41.

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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.<sup>8</sup>

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.<sup>9</sup> 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

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<sup>8</sup> See generally 21 USC 355(d).

<sup>9</sup> 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.

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154 Approval of a drug in pediatric patients<sup>10</sup> 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 population<sup>11</sup>
- 164
- 165 • One pediatric population that allows extrapolation of effectiveness to another  
166 pediatric population<sup>12</sup>
- 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 assessments<sup>13</sup> 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.<sup>14</sup>

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

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

<sup>12</sup> 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.

<sup>13</sup> 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).

<sup>14</sup> 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)).<sup>15</sup> 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.<sup>16</sup>

## **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.<sup>17</sup> 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.,

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

<sup>16</sup> See generally 21 CFR 201.56(a).

<sup>17</sup> See 21 CFR 201.57(c)(2).

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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 FEV<sub>1</sub> 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

### **A. Indication**

252

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.

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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



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- 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)).<sup>18</sup> 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).<sup>19</sup>

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<sup>18</sup> 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*.

<sup>19</sup> 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*.

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### **B. Limitations of Use**

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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,

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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

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

405

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

408

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

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

#### Limitations of Use

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

431

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

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

### Limitations of Use

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

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

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

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

### Limitations of Use

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

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

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

- DRUG-X is indicated for the management of elevated plasma uric acid 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.

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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           1. *Identification of Outcomes, Endpoints, and Benefit(s) the Drug Conveys*

541  
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

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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)).<sup>20</sup>

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.<sup>21</sup>
- 608

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<sup>20</sup> 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.

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

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### **4. Preferred Wording and Wording Generally To Avoid<sup>22</sup>**

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

#### **a. “Reduce the risk” versus “prevent”**

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

#### **b. “Only”**

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

#### **c. “Also indicated”**

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

#### **d. Product identification in the indication**

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

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

## **D. Formatting the INDICATIONS AND USAGE Section**

### **1. Format for Multiple Indications**

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

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<sup>22</sup> See generally 21 CFR 201.56.



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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

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.  
665

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666

667

# Attachment 6



## 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.