California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member, President
Nicole Thibeau, Licensee Member

a. Presentation on the Canadian Medication Incident Reporting and Prevention System (CMIRPS) by ISMP Canada

Background
As the Board learned through its evaluation of medication errors and efforts undertaken by other jurisdictions, there are Canadian provinces that require medication errors to be reported to an entity for evaluation. The receiving entity is ISMP Canada.

During the Committee's discussion on implementation of AB 1286, members determined it was appropriate to receive presentations from entities that currently receive and review medication error reports.

Summary of Committee Discussion
During the January 2024 meeting, members received a presentation from ISMP Canada discussing their implementation of medication error reporting as well as the deliverables released by ISMP Canada to promote patient safety. This was one of several presentations received by the Committee to help inform its decisions related to defining scope of work requirements required as part of the Invitation for Bid release for entities interested in acting as the Board-approved entity for medication error reporting and analysis.

Attachment 1 includes a copy of the presentation slides.

b. Presentation on Medication Error Reporting by the Agency for Healthcare Research and Quality

Background
The Agency for Healthcare Research and Quality (AHRQ) is "the lead federal agency charged with improving the safety and quality of healthcare for all Americans. AHRQ

develops the knowledge, tools, and data needed to improve the healthcare system and help consumers, healthcare professionals, and policy makers make informed decisions."

As part of its role, AHRQ administers the Patient Safety Organization certification process. AHRQ also manages the Network of Patient Safety Databases (NPSD). The NPSD contains non-identifiable data derived from information voluntarily submitted by patient safety organizations. The data makes it possible to identify and track patient safety concerns for the purpose of learning how to mitigate patient safety risks and reduce harm across healthcare settings nationally.

Summary of Committee Discussion
During the January 2024 meeting, the Committee also received a presentation by AHRQ on voluntary medication error reporting at the federal level through patient safety organizations.

Attachment 2 includes a copy of the presentation slides.

c. Presentation on the State Contracting Process by the California Department of Consumer Affairs

Consistent with the Committee's discussion during its October 2023 meeting, the Board must contract with an entity to serve as the entity approved by the Board to receive medication error reports under new Business and Professions Code (BPC) section 4113.1. The state contracting process has standard requirements that all contracts must include; however, there is also an opportunity to define some of the provisions of the scope of work specifically related to the contract.

Summary of Committee Discussion
During the January 2024 meeting, the Committee also received a presentation by the Department of Consumer Affairs (DCA) Business Services Office on the state contracting process.

Attachment 3 includes a copy of the presentation slides.

d. Scope of Work and Contract Requirements for Inclusion in the Invitation for Bid for Interested Parties Seeking to Serve as the Approved Entity under Business and Professions Code section 4113.1

Summary of Committee Discussion
Following the various presentations at the January 2024 meeting, members and stakeholders considered a number of questions related to the provisions for the scope of work for the contract with the entity that will receive and analyze medication errors, consistent with statutory provisions. Provided below are the questions considered and

summaries of the comments provided by members and stakeholders.

1. Does the Committee wish to provide feedback on the required elements of the medication error reports? Board staff recommend that at a minimum the following elements be included in error reporting.[1]
    a. **Pharmacy Unique Identifier (Unique Identifier to be established by the contracted vendor)**
    b. Type of Pharmacy (drop down menu) (Suggested options, chain (defined as 75 or more); nonchain; specialty pharmacy; closed door; hospital outpatient; other please specify
    c. **Date of incident**
    d. **Type of event (drop down menu) (AHRQ includes types of events followed by subcategories)**
    e. **Stage of process where error occurred (drop down menu)**
    f. **Type of patient (human, veterinary or unknown)**
    g. **Age of patient (drop down menu) (AHRQ include patient date of birth)**
    h. **Sex**
    i. **Patient harm (drop down menu and subcategories of harm, e.g., severe, moderate, etc. as defined)**
    j. Type of staff involved (drop down menu, may select more than one)
    k. Staffing at the time the event occurred or on the date the incident occurred
    l. Volume of work on the date of the incident (fill-in specified number, *e.g.*, number of new prescriptions, number of refill prescriptions, number of vaccines administered, etc.)
    m. Was technology involved (yes/no, if yes, brief description)
    n. **Medication involved** (narrative, drug name, strength and quantity prescribed)
    o. **Prescription Details (*e.g.*, e-prescribed, faxed, written, transferred, etc. (drop down menu)**
    p. **Prescriber type (drop down menu)**
    q. **Contributing factors (drop down and narrative)**
    r. **Report date**

Members discussed the proposed data elements and considered if additional elements should also be included. The additional elements include addition of either race or culture and a data element that would allow the reporting pharmacy to indicated if a language barrier contributed to the event. In addition, Committee members discussed if the data elements should include sex or gender, and if the data reporting regarding the use of technology should include a drop down menu. Members expressed concern that if the additional elements were not collected, disparities in care may not be identified and noted that an "if known" clarification could be added to the requirement to indicate that the element only needs to be reported if the pharmacy has the information.

Public comment on the data elements varied. Some commenters urged the Committee to only require essential elements with one commenter suggesting that the reporting

[1] Staff note that the community pharmacy common format established by AHRQ provides the foundation for many of the recommendations offered here. The items in bold are reporting elements included in the common format.

elements should not be specified and should rather be determined by a patient safety organization. Commenters questioned the need for collecting data on sex and race and indicated that collection of a "pharmacy unique identifier" was not appropriate. Public comment also suggested that the required elements should include if patient consultation was required and if pharmacist impairment was a contributing factor for the error.

After public comment, the committee expressed concern about too many required data elements that may make reporting difficult or create barriers to reporting. The database perhaps should be limited to elements found in AHRQ database and commonly found in pharmacy system databases. For example, race, culture/ethnicity and language barrier issues are not elements collected as a part of the pharmacy record. The medication error reporting database is not a replacement for the existing internal pharmacy quality assurance documentation as required by law and regulation.

Items not included in the list above, but included in the AHRQ community pharmacy common format include:

- Event ID (a unique event ID assigned to each error.)
- Report type (incident, near miss and unsafe condition) **Note**: Pharmacy Law only requires reporting of errors as defined in BPC section 4113.1. Near misses are not required to be reported.
- Was medication prescribed?
- Was medication given?

2. Does the Committee agree that the entity will provide a process or processes to collect data from all required reporters and will report, summarize, and evaluate data to provide recommendations?

Members noted the need for a single entity to be the approved entity.

Public comment suggested that if information is released by the approved entity, it should be provided to all reporting entities.

3. Does the Committee wish to specify the frequency within which data is provided to the Board, *e.g.*, quarterly, semi-annually, annually, upon request, etc.?

Members noted that data should be reported to the Board quarterly, at least at the beginning of implementation.

No public comments were received.

4. How frequently does the Committee prefer the entity to provide summary reports on its findings regarding trends that may be published and disseminated?

Members commented that summary reports regarding trends should be provided at least semi-annually.

Public comment suggested that some information may need to be released immediately depending on the nature of an event.

5. How frequently does the Committee prefer the entity to develop and disseminate information gained from the reporting to improve patient safety such as recommendations or best practices?

Members concluded that information should be released at a minimum annually.

Public comments indicated that federal law allows pharmacies to report to a PSO and that pharmacies currently work with PSOs to identify best practices.

6. Are there certain types of events (*e.g.*, patient death) that the Committee believes should be identified immediately and potentially released as a safety alert within a specified timeframe?

The Committee agreed that the scope of work should require opportunity for the Board to immediately release of information such as patient safety alerts based on the urgency and severity of medication errors reported. However, such information released should be evaluated to minimize any unintended consequences.

No public comments were received.

7. How will ad-hoc or custom reports be requested if further information is desired by the Board?

Members agreed that the scope of work needs to include provisions for ad-hoc or custom reports.

No public comments were received.

8. Does the Committee wish to delegate a member to serve on the panel responsible for reviewing the proposals and selecting the vendor?

Members agreed that a member should serve on the panel and agreed that Chairperson Serpa is the appropriate member to participate.

Public comment agreed that a Board member should serve on the panel. The comment also suggested that other organizations (including possibly PSOs) could

provide presentations to the Committee.[2] Other public comment suggested that the Board should provide a flowchart. It was noted that many pharmacies are already reporting to PSOs and showing the process on how pharmacies can report either directly or via their PSO to the entity would be helpful.

Note: BPC section 4113.1 provides that approval of an entity resides with the Board. Following the state contracting process, and prior to awarding the contract, the Board will have the opportunity to review information on the winning bidder and if deemed appropriate by the Board, approve the entity prior to awarding the contract.

9. As the contract will be fully funded through licensees reporting to the entity, does the Committee believe the cost to be assessed to each pharmacy reporting should be a factor in determining the entity to receive the award of the bid?

Members agreed that the cost to reporting pharmacies needs to be considered as a factor in determining the awarding of the bid.

Public comment suggested that the cost criteria should detail how the costs would be apportioned.

10. Does the Committee believe the entity needs to provide a variety of means for pharmacies (or their agents) to submit the data reports, *e.g.*, through a portal, emailing a datafile, 3rd party such as PSO, etc.

Members agreed that the entity needs to provide a variety of means to transmit the medication error reports.

Public comment also spoke in support of the requirement indicating that efforts need to be made to reduce the burden of reporting. Other comment indicated that the Board should allow PSOs to act as a reporting body to the entity on behalf of the pharmacy. (Staff notes that the law already establishes this requirement.)

Following the Board's discussion, it is recommended that the Board consider a motion to officially appoint Committee Chairperson Maria Serpa to serve on the panel responsible for review of proposals and selection of a vendor.

> **Recommended Motion**: Appoint Maria Serpa to serve on the panel responsible for review of proposals and selection of a vendor to serve as the Board's approved entity consistent with Business and Professions Code Section 4113.1.

Subsequent to the meeting, and in consultation with DCA's Business Services Office, it was determined appropriate to release a Request for Information to ensure that

[2] **Note**: As included in the presentation by the Department of Consumer Affairs, presentations by potential bidders can be part of the RFP process.

stakeholders have additional opportunities to provide comments on the questions considered by the committee. Interested parties should contact Miriam.lopez@dca.ca.gov to be added to the interested parties list.

Note: BPC section 4113.1 provides that approval of an entity resides with the Board. Following the state contracting process, and prior to awarding the contract, the Board will have the opportunity to review information on the winning bidder and if deemed appropriate by the Board, approve the entity prior to awarding the contract.

Attachment 4 includes written comment received following the Committee meeting.

e. Draft Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Background
Assembly Bill 1286 included several significant patient safety elements. As part of the Committee's prior discussion on implementation of Assembly Bill 1286, members requested that staff prepare a list of Frequently Asked Questions that the Board could release to assist stakeholders in gaining an understanding of the requirements of the measure.

Following the October 2023 Committee meeting, staff prepared draft FAQs on the various provisions of AB 1286.

Summary of Committee Discussion and Action.
During the January 2024 meeting, members discussed the draft FAQs and noted agreement with the draft as presented.

Public comment suggested several changes to the document including suggesting that the Board include examples within various items included in the FAQs. Members were subsequently advised by counsel that the addition of examples was not appropriate.

Following discussion by the Committee and public comment, the Committee is offering the following:

Motion: Recommend approval of the FAQs related to Assembly Bill 1286.

Attachment 5 includes a copy of the draft FAQs.

f. Proposed Revisions to Frequently Asked Questions Regarding the Use of Mobile Units

Relevant Law
BPC section 4110.5 establishes authority for a county, city and county, or certain special

hospital authorities to operate one or more mobile units to provide prescription medication within its jurisdiction to individuals meeting specified criteria.

Background
Assembly Bill 663 (Haney, Chapter 539, Statutes of 2023) amended BPC section 4110.5 to allow for the use of one or more mobile units. Further, pursuant to the amendments enacted by AB 663, a mobile unit may now carry Schedule III, Schedule IV, or Schedule V controlled substances approved by the FDA for the treatment of opioid use disorder under specified conditions.

During the Committee's October 19, 2023 meeting, members noted the need to update the existing FAQs to reflect the recent changes in the law.

Summary of Committee Discussion and Action
During the January 2024 meeting, members discussed the updated draft of the FAQs. Following public comment, the Committee determined clarification of Question 8 (which currently states "at the end of the day") was needed to clarify when the mobile unit needs to be stored. The Committee is offering the following:

> **Motion**: Recommend approval of the revised updated FAQs related to mobile units.

Attachment 6 includes a copy of the updated FAQs incorporating the change to Question 8.

g. Draft Self-Assessment Form for Surgical Clinics

Relevant Law
BPC section 4192 generally establishes the requirement for a surgical clinic to have a consulting pharmacist that is required to visit the clinic regularly and at least quarterly. This section now also includes completion of a self-assessment form as a means to promote compliance through self-examination and education.

Background
The establishment of a self-assessment process for surgical clinics was another key component of AB 1286. As required by the statute, the self-assessment form must be completed before July 1 of every odd-numbered year by the consulting pharmacist. Consistent with the self-assessments used for other license types, the self-assessment form generally restates the relevant law section and includes the reference section. The self-assessment form itself does not create any legal requirements.

Summary of Committee Discussion and Action
During the January 2024 meeting, members considered the draft self-assessment form. Members noted agreement with the draft self-assessment form.

Public comment expressed appreciation for the Board creating a self-assessment process for surgical clinics and noted it would be helpful for all surgical clinics, not just those regulated by the Board. Several elements of the form were discussed with the need for counsel to confirm the information included on the self-assessment form including 5.7, 5.8, 5.9, 6.6, and 8.1 and 8.2.

Motion: Recommend approval of the draft Surgical Clinic Self-Assessment Form.

Attachment 7 includes the draft self-assessment form including changes identified by Committee chair consistent with authority delegated by the Committee. Changes are reflected in underline and strikethrough.

h. Possible Action to Amend California Code of Regulations, Title 16, Sections 1715 and 1784 and Self-Assessment Forms 17M-13, 17M-14, and 17M-26, Incorporated By Reference

Relevant Law

California Code of Regulations, title 16, section 1715(c) establishes the self-assessment requirements for the pharmacist-in-charge of a community pharmacy to complete a "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Section 1715(c) further establishes a similar requirement for the pharmacist-in-charge of a hospital pharmacy serving inpatient consumers to complete a "Hospital Pharmacy Self-Assessment." Both forms are incorporated by reference in the regulation.

California Code of Regulations, title 16, section 1784(c) establishes the self-assessment requirement for a wholesaler or third-party logistics provider, through its designated representative-in-charge or responsible manager, to complete a "Wholesaler/Third Party Logistics Provider Self-Assessment." The form is incorporated by reference in the regulation.

Background

As pharmacy law is very dynamic, on an annual basis, the self-assessment forms must be updated to reflect the most current law. During discussions on the proposed updates to the self-assessment forms in February 2023, given that the forms restate law and do not create requirements not already established in statute and regulation, the Board determined updates to the forms could best be facilitated through a streamlined Section 100 regulation process.[3]

Regrettably, staff was recently advised by the Office of Administrative Law (OAL) that updates to these forms cannot be made via this streamlined process.

Summary of Committee Discussion and Action

[3] Section 100 regulations are "changes without regulatory effect." (See Cal. Code Regs., tit. 1, § 100(a).)

During the meeting, members reviewed the proposed updates to the self-assessment forms. The forms incorporate the changes considered by the Committee last year and now also reflect additional changes to incorporate more recent changes in pharmacy law. Members noted agreement with the proposed changes.

Public comment suggested that the Board should remove provisions on the community pharmacy self-assessment form and hospital self-assessment form related to pharmacists and pharmacy technicians' completion of continuing education related to cultural competency.

The Committee is offering the following:

> **Motion**: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, sections 1715 and 1784 as proposed to be amended and self-assessment forms 17M-13, 17M-14, and 17M-26 incorporated by reference. Authorize the executive officer to further refine the language consistent with the Board's discussion and to make any nonsubstantive changes.

Attachment 8 includes a copy of proposed amended regulatory text and the updated forms. The changes are highlighted with strikethrough representing text that has been removed and underline representing text being added.

i. <u>Enforcement Statistics</u>

During the first six months of the fiscal year, the Board received 1,639 complaints and closed 1,371 investigations. The Board has issued 95 Letters of Admonishment, 430 Citations and referred 142 cases to the Office of the Attorney General. The Board has revoked 35 licenses, accepted the disciplinary surrender of 9 licenses, formally denied 2 applications, and imposed other levels of discipline against 33 licensees and/or applicants.

As of January 1, 2024, the Board had 1,582 field investigations pending. On the following page is a breakdown providing more detail in the various investigation processes:

	Jan. 1, 2023		Apr. 1, 2023		Jul. 1, 2023		Oct. 1, 2023		Jan. 1, 2024	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	80	12	116	6	59	8	88	22	152	15
Cases Under Investigation	853	129	874	138	942	141	982	138	1037	146
Pending Supervisor Review	199	85	146	22	164	31	183	47	286	77
Pending Second Level Review	226	55	245	36	79	22	82	22	81	21
Awaiting Final Closure	92	35	8	43	148	12	34	13	26	19

The Committee did not receive any public comments on the enforcement statistics presented.

Attachment 9 includes the enforcement statistics for the first six months of the fiscal year.

Attachment 1

Community Pharmacy Medication Incident Reporting in Canada

California State Board of Pharmacy

January 23, 2024

ZERO Preventable Harm From Medications

Institute for Safe Medication Practices Canada

Land Acknowledgement

We acknowledge we are hosted on the lands of the Mississaugas of the Anishinaabe, the Haudenosaunee Confederacy and the Wendat. We also recognize the enduring presence of all First Nations, Métis and the Inuit peoples.[1] We are grateful to live, work and play on this land and we want to contribute to the implementation of the Truth and Reconciliation Commission's eight health-related Calls to Action.

Nous tenons à souligner que nous sommes accueillis sur le territoire traditionel des Mississaugas, des Anichinabés, des Haudenosaunees et des Wendats. Nous voulons également reconnaître la pérennité de la présence des Premières Nations, des Métis et des Inuits. Nous sommes reconnaissants de vivre, de travailler et de jouer sur ce territoire et nous voulons contribuer à la mise en œuvre des huit appels à l'action de la Commission de vérité et de réconciliation en matière de santé.

Find your land acknowledgement at https://native-land.ca/

[1] https://www.tdsb.on.ca/Community/Indigenous-Education/Resources/Land-Acknowledgement

Session Overview

- Melissa Sheldrick's Story
- Medication Incidents & ISMP Canada's Unique Mandate
- Reporting, Learning & Acting on Med Incidents
- How Each Pharmacy Contributes Their Incident Data
- Provincial and National Shared Learning and Improvements

ISMP Canada Presenters

Melissa Sheldrick,
BA Soc, MSc Ed
Patient and Family Advisor

Sylvia Hyland, RPh, BScPhm, MHSc
Vice President, Operations & Privacy Officer

Enna Aujla
Director, Community Pharmacy Reporting & Learning

Chief Executive Officer

Melissa's Story

Andrew Sheldrick died in 2016 because of errors made during the dispensing process of his compounded medication. The main error was a substitution of Andrew's tryptophan with baclofen.

Prescribed Tryptophan Dose:
3-gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime.

Melissa's Story

What is a medication incident?

A medication incident is a mistake with medicine, or a problem that could cause a mistake with medicine.

Harm Related To Medications

- As many as **1 in 10 hospitalizations** in OECD countries may be caused by a medication-related event
- As many **one in five inpatients** experience medication-related harms during hospitalization
- Together, costs from avoidable admissions due to medication-related events and added length of stay due to preventable hospital-acquired medication-related harms total over **USD 54 billion in OECD countries***

*de Bienassis, K., et al. (2022), "The economics of medication safety: Improving medication safety through collective, real-time learning", *OECD Health Working Papers*, No. 147, OECD Publishing, Paris, https://doi.org/10.1787/9a933261-en.

A Trusted Partner

Strengthening medication safety through timely learning, sharing, and acting to improve health care.

ISMP Canada is a national, **independent, not-for-profit** organization that purposefully partners with organizations, practitioners, consumers, and caregivers to advance medication safety in all healthcare settings.

ismp CANADA

For over 20 years…

Reporting, Learning and Acting

ISMP Canada is a lead partner in the Canadian Medication Incident Reporting and Prevention Program(CMIRPS)

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

CMIRPS collaborates with local, provincial and national partners to prevent and respond to medication incidents across Canada

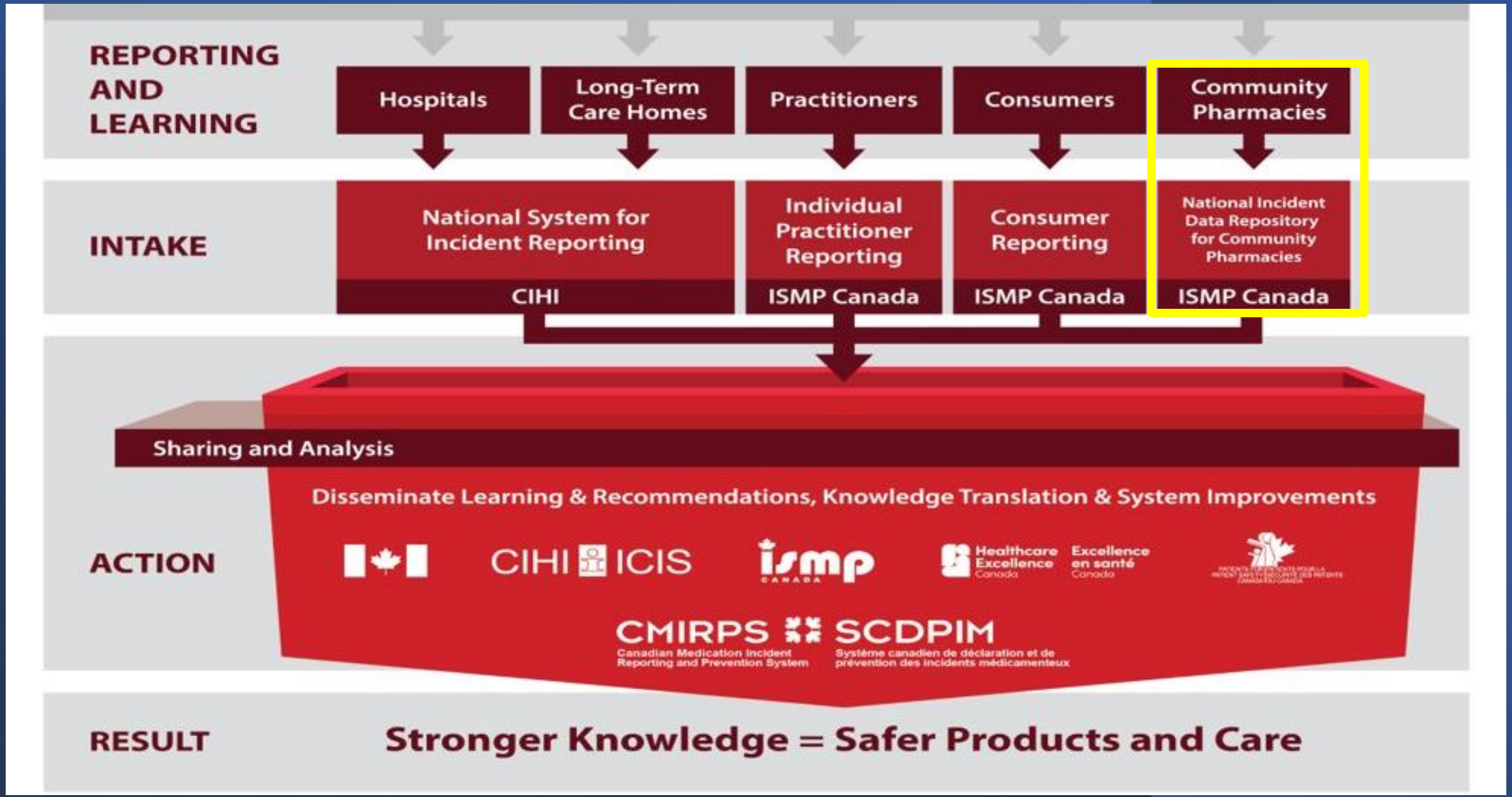
Medication incident occurs (includes harmful events, no-harm events, near misses and underlying conditions that could lead to harmful incidents)

The incident is reported through a CMIRPS channel by healthcare organizations, individual practitioners, consumers

Expert review, analysis & trend identification is conducted by ISMP Canada, including targeted review of additional data from the Canadian Institute for Health Information

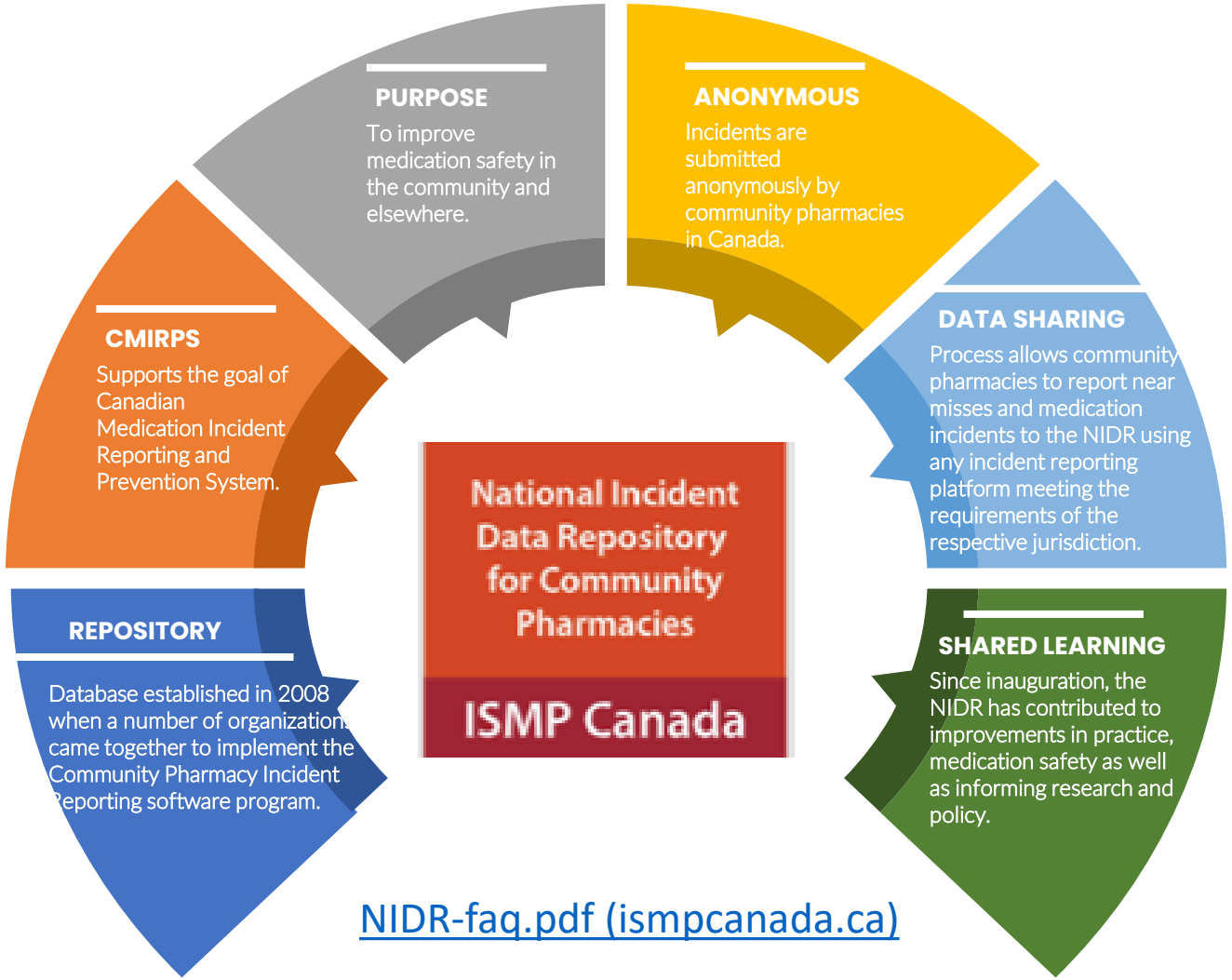
Action & recommendations are made via safety bulletins, alerts, stakeholder communication

Facilitation of change: measures to prevent reoccurrence are put in place

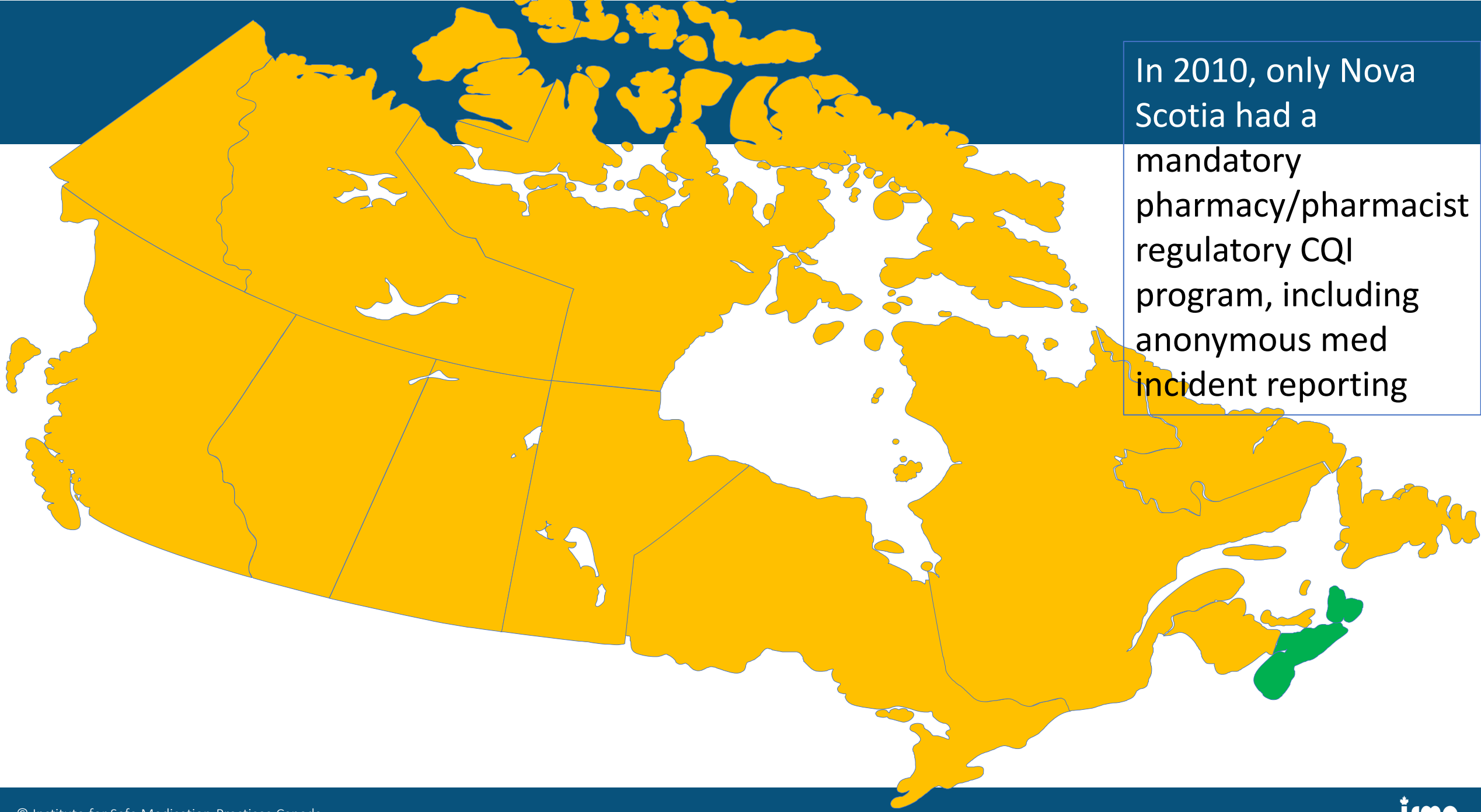

REPORTING AND LEARNING
Hospitals
Long-Term Care Homes
Practitioners
Consumers
Community Pharmacies
INTAKE
National System for Incident Reporting
CIHI
Individual Practitioner Reporting
ISMP Canada
Consumer Reporting
ISMP Canada
National Incident Data Repository for Community Pharmacies
ISMP Canada
Sharing and Analysis
ACTION
Disseminate Learning & Recommendations, Knowledge Translation & System Improvements
CIHI ICIS
ismp CANADA
Healthcare Excellence Canada
Excellence en santé Canada
CMIRPS
Canadian Medication Incident Reporting and Prevention System
SCDPIM
Système canadien de déclaration et de prévention des incidents médicamenteux
RESULT
Stronger Knowledge = Safer Products and Care

National Incident Data Repository for Community Pharmacies (NIDR)

National Incident Data Repository (NIDR)



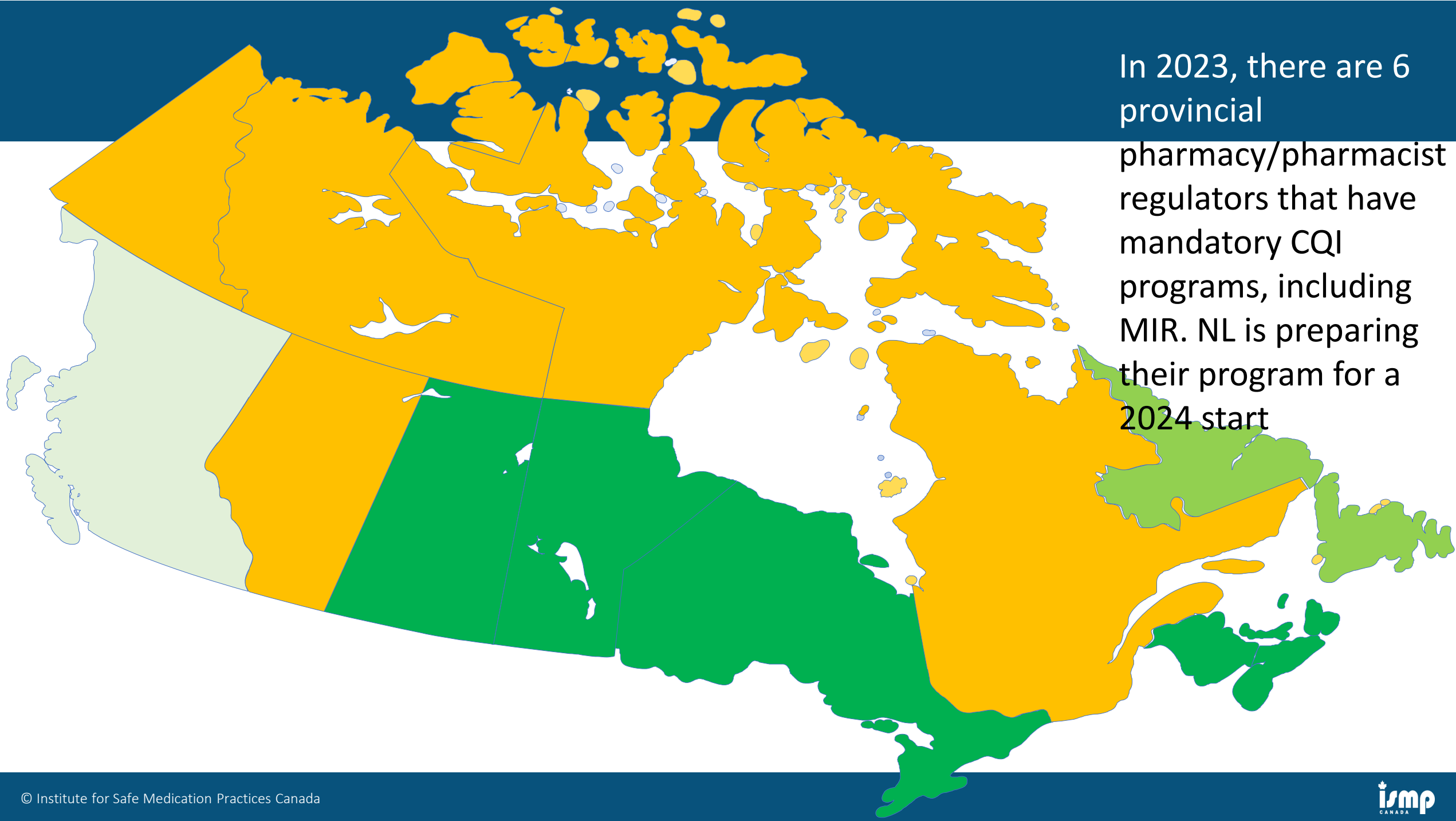
[NIDR-faq.pdf (ismpcanada.ca)]



In 2010, only Nova Scotia had a mandatory pharmacy/pharmacist regulatory CQI program, including anonymous med incident reporting

Innovation

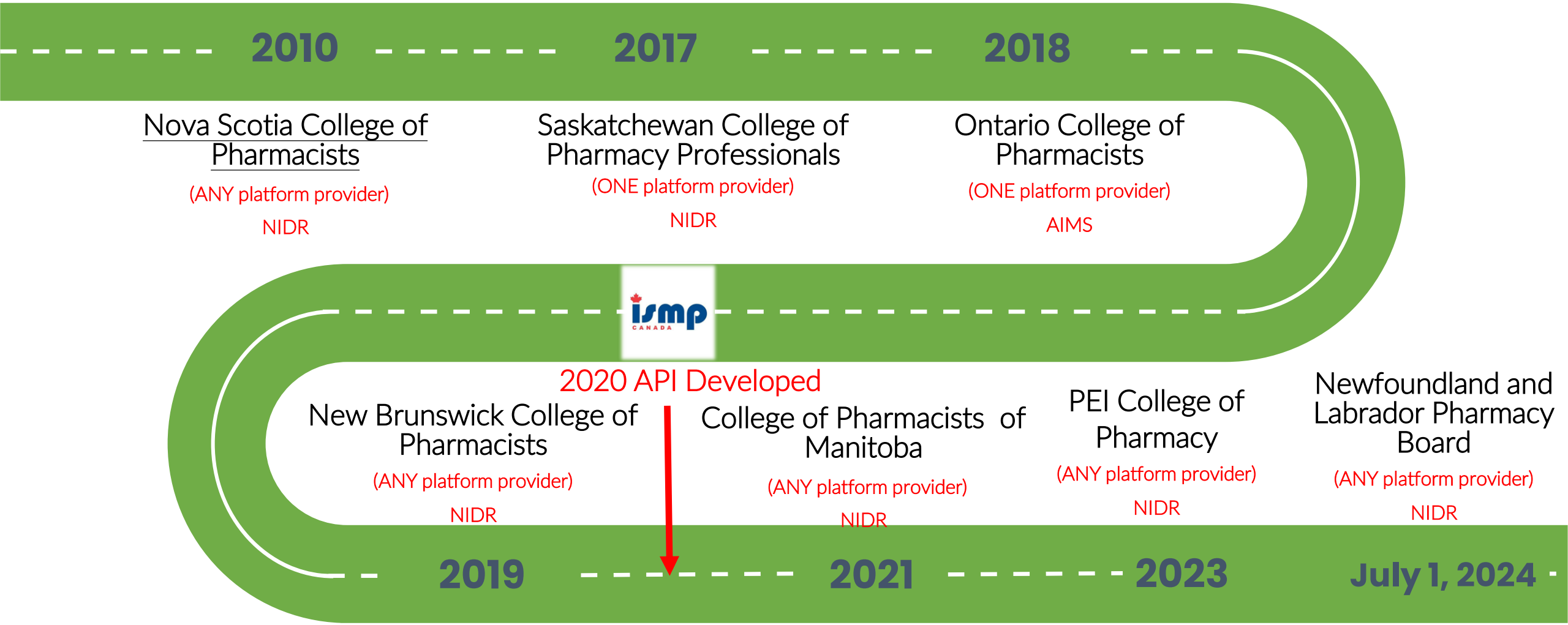
OCP invited Melissa to be part of the initial task force to craft this program and determine its needs. They had never invited a member of the public to be part of this type of task force.



In 2023, there are 6 provincial pharmacy/pharmacist regulators that have mandatory CQI programs, including MIR. NL is preparing their program for a 2024 start

Provincial Regulatory Mandatory Program Timeline

Pan-Canadian (2023)



NAPRA Model Standards

"Continuous quality improvement and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/ territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care."

ISMP Canada collaborating with Provincial Regulators

Saskatchewan College of Pharmacy Professionals – COMPASS

"The strength of the COMPASS program comes from Saskatchewan community pharmacies contributing to a national database called Canada's National Incident Data Repository for Community Pharmacies, which contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS)."

College of Pharmacists of Manitoba - Safety IQ

"Safety expert James Reason argued that "the most detrimental error is failing to learn from an error." **When healthcare professionals share what they learn from incidents within teams and across disciplines, safety improvements are passed along to all Canadians.** Through Safety IQ, community pharmacy teams share valuable learnings to improve patient outcomes on team, provincial, and national levels."

Nova Scotia College of Pharmacists - SafetyNETRx

"By submitting to a national database, pharmacies enable the identification of safety-related trends and patterns that can be communicated across the profession, not just in their own pharmacy.

ISMP Canada collaborating with Provincial Regulators

Newfoundland and Labrador Pharmacy Board - MedSTEP NL

"CQI and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care."

New Brunswick College of Pharmacists

"Pharmacy managers must ensure that **pharmacy professionals anonymously report medication errors (medication incidents that reach the patient) to an external, central Canadian database**."

PEI College of Pharmacy

The Council of the PEI College of Pharmacy has **adopted the NAPRA Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals.**" "The College will receive aggregate data (deidentified and anonymous) to monitor trends and participation in the mandatory medication incident reporting program (at the pharmacy level.)"

How Each Pharmacy Contributes to the NIDR

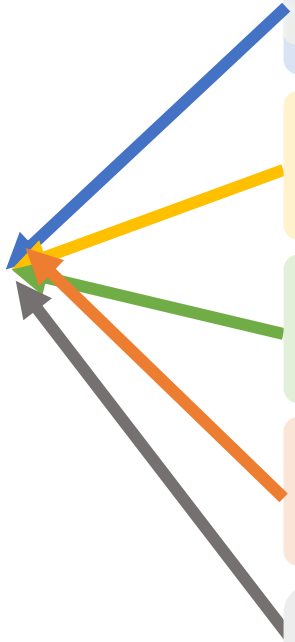
Enabling Data Submission Across Different Reporting Platforms

Platforms Reporting Into NIDR

NIDR

A component of CMIRPS

API



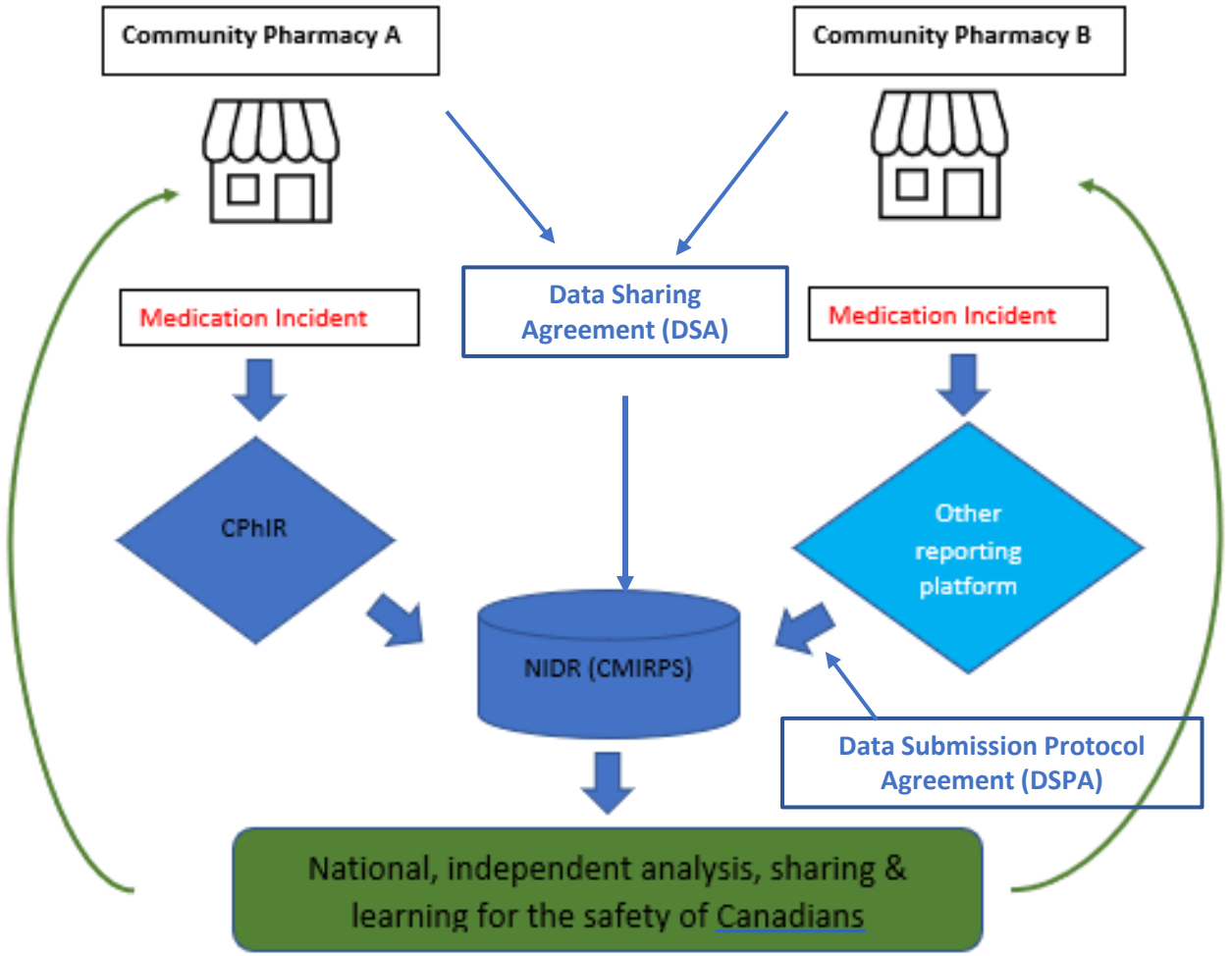
- **Community Pharmacy Incident Reporting (CPhIR)**
- **Third Party Platform Provider** (Vendor 1)
- **Third Party Platform Provider** (Vendor 2)
- **Third Party Platform Provider** (Vendor 3)
- **In-House Corporate Developed Platform**

API = Application Programming Interface

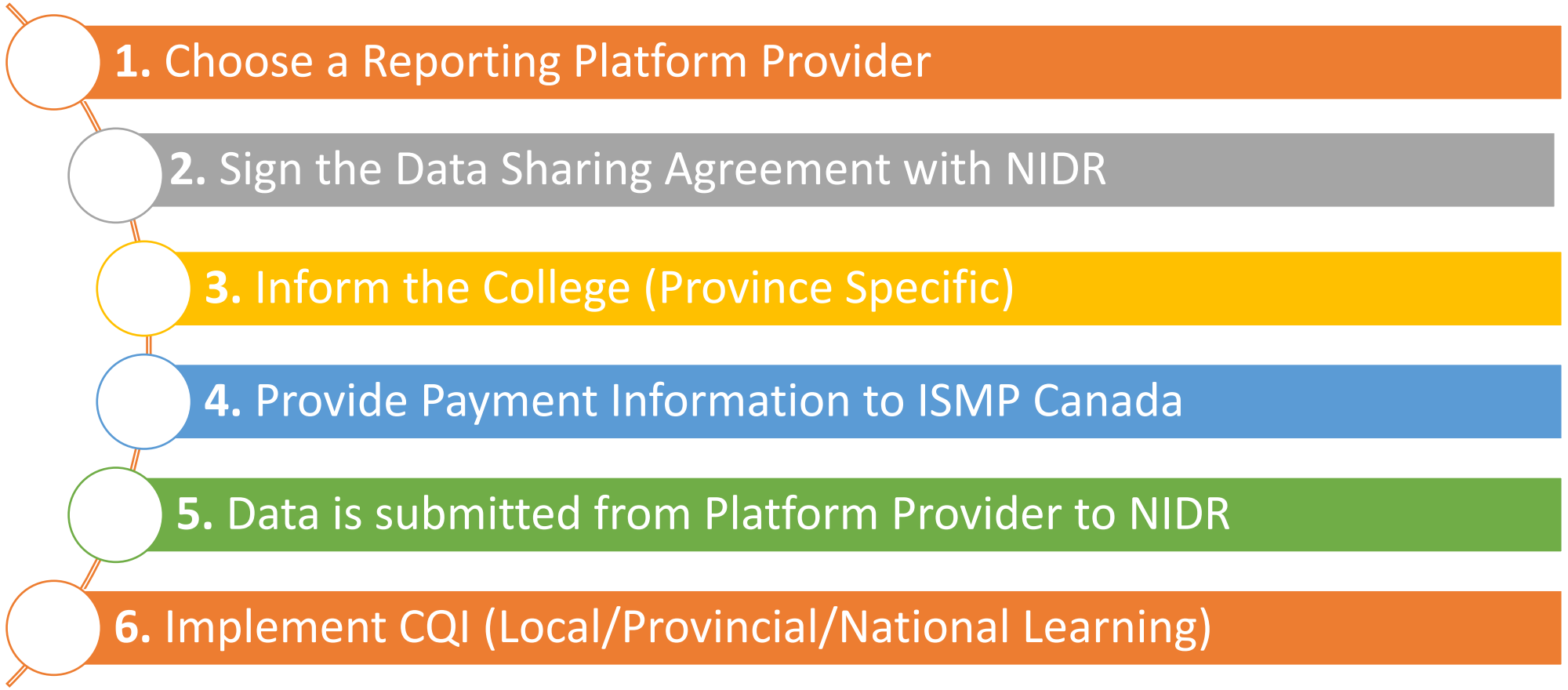
Community Pharmacy Reporting and Learning Process

The Reporting and Learning Process

Community Pharmacy Reporting Processes for Submission of Data to the NIDR



Summary of Pharmacy Steps



What does the Pharmacy Report?
NIDR Minimum Data Set – 7 Mandatory Fields

Mandatory Field	Some Examples of Allowable Responses
Date incident occurred	Year, Month, Day Required
Type of incident	Incorrect patient, incorrect drug, incorrect quantity, drug therapy problem-documented allergy, drug therapy problem-contraindication,
Incident discovered by	Pharmacist, Patient, Prescriber, Caregiver, Pharmacy Assistant, Nurse
Medication System Stages Involved in this Incident	Prescribing, Rx Order Entry, Prescription Preparation/Dispensing, Administration, Monitoring/Follow-up
Medications involved if it was a medication related incident	Drug Product Name, Drug Identification Number (DIN)
Degree of Harm to Patient due to Incident	No Error (Medication Not Dispensed/Near Miss), No Harm, Mild Harm, Moderate Harm, Severe Harm, Death
Incident Description / How the Incident was Discovered	Free Text Field

What does the Pharmacy Report? Examples of Optional Fields

Some Optional Field Examples	Some Examples of Allowable Responses
Contributing Factors	Critical patient information missing-weight, Drug name-look/sound alike names, lack of quality control-independent check system,
Incident Background Information	Hand-written prescription, narcotic/controlled drug, Rx Delivery, Log prescription, e-prescription
Gender	
Age	Ranges: 0-28 days, 28 days-18 years, 18 years-65 years, > 65 years
Time Incident Occurred	Morning, Afternoon, Evening, Overnight, Unknown
Actions Taken at Pharmacy Level	Free Text Field
Shared Learning/Comments	Free Text Field

Data Analysis
Shared Learning
Practice Supports

Analysis by Multidisciplinary Team

Incident reports

Hospitals

Pharmacies

Practitioners

Consumers

Facilities

Multidisciplinary Analysis Team

Pharmacists

Nurses

MDs

Patient & Family Advisor

Others

Outputs

Alerts

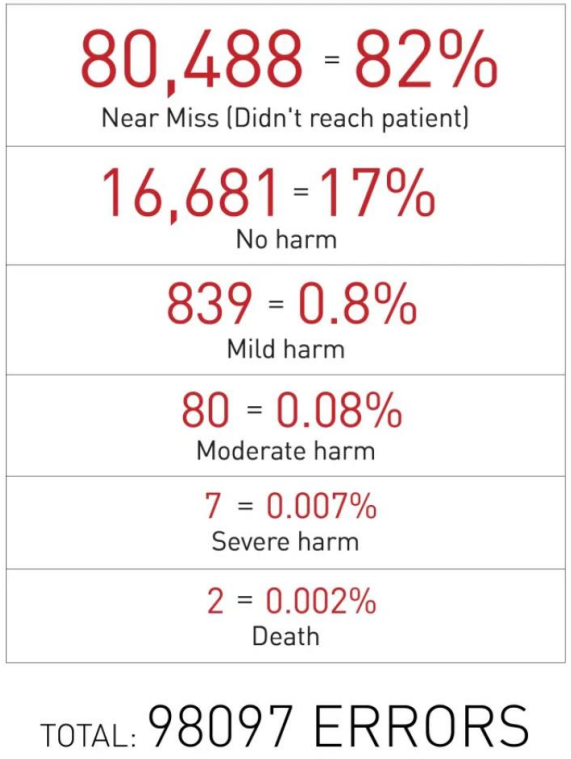
Bulletins

Practice Improvement Tools

Support for Knowledge Translation

Nova Scotia Reporting Over a 7-year Period

NS pharmacy errors, 2010 - 2017



Key Findings

- 301 Community Pharmacies
- 98,097 quality-related events
- 0.95% (*n*=928) were associated with patient harm
- Most common types of quality-related events reported were incorrect dose or frequency, incorrect quantity, and incorrect drug
- Most of the quality-related events occurred at order entry
- There are key differences in the types of reports from community pharmacies and those from other settings

Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis. 2018, CMAJ Open. Boucher, A., et al. Available: Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis (cmajopen.ca)

Data Reports Quantitative

Number of reports

Types of incidents

Levels of harm

Tips from nationally-derived qualitative analyses

ismp CANADA

National Incident Data Repository Safety Brief

Manitoba Data

5,204 reports received from community pharmacies
from April 1, 2017 to September 30, 2022

Reporting period: April 2022 – September 2022

Reports Received	**1,306**
Types of Incidents (including near misses) **(Top 5)**	
Incorrect dose/frequency	263
Incorrect drug	214
Incorrect strength/concentration	180
Incorrect patient	141
Incorrect quantity	106
Levels of Harm	
No Error (e.g., Near Miss)	546
No Harm	674
Mild Harm	81
Moderate Harm	4
Severe Harm	0
Death	1

National Learning

Manitoba community pharmacies contribute to national learning and safety initiatives that incorporate learning from reported medication incidents and suggest system safeguards to prevent patient harm.

One of the most frequently reported types of errors in community pharmacy is incorrect dose/frequency. This is the case for incidents involving direct oral anticoagulants (DOACs).

Thrombosis Canada's monitoring checklist considers several factors to help health care providers optimize the safe and effective use of DOACs.

SAFETY TIP: Confirm the indication and patient-specific factors (e.g., renal function, weight) for a DOAC with the patient or prescriber to assess the appropriate dose, frequency, and duration.

SAFETY TIP: Pharmacists are uniquely positioned to communicate with patients at every refill. Because DOACs, unlike warfarin, do not undergo regular therapeutic monitoring, it is important to emphasize adherence during patient counselling.

Additional safety recommendations can be found in ISMP Canada Safety Bulletins:
https://ismpcanada.ca/safety-bulletins/

LEARN ✓ SHARE ✓ ACT ✓

More than 295,000 reports of medication incidents have been submitted to the National Incident Data Repository for Community Pharmacies (NIDR) since 2008.

Safety. Improvement. Quality.

National Incident Data Repository | Référentiel de données nationales sur les incidents

CMIRPS SCDPIM

National Incident Data Repository for Community Pharmacies
National Snapshot

July 2023

From January 1 to December 31, 2022, a total of 49 650 reports of medication incidents were submitted to the National Incident Data Repository for Community Pharmacies (NIDR) from participating provinces. Most of the reports described near-miss or no-harm incidents; 1.21% (n= 603) of the incidents were associated with mild, moderate, or severe harm, or death. Analysis of incidents has informed the shared learning offered in ISMP Canada Safety Bulletins and provincial NIDR Safety Briefs.

The focus of this NIDR National Snapshot is the 2022 dataset of medication incidents for which "critical patient information missing" was specified as a contributing factor. Reports of 315 incidents with detailed descriptions were included in a multi-incident analysis using the Canadian Incident Analysis Framework.[1] The findings of this analysis (Figure 1) and strategies for improvement (Box 1) are presented here.

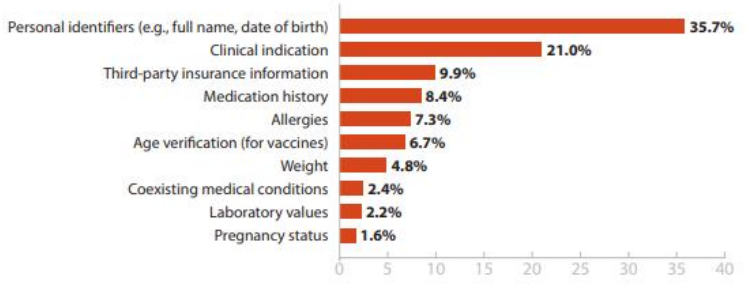


FIGURE 1. Types of critical patient information missed during the processes of prescription order entry, pharmacist clinical check, vaccine administration, and/or prescription delivery.

The National Incident Data Repository for Community Pharmacies (NIDR) is a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

The NIDR contains more than 300 000 reports of medication incidents that have been shared by community pharmacies since 2008. ISMP Canada is committed to analyzing these reports and developing and disseminating learning, with the goal of improving health care systems and medication safety.

Thank you for reporting medication incidents. Your efforts help to inform the "learn, share, and act" cycle!

ismp CANADA

National Incident Data Repository | Référentiel de données nationales sur les incidents

CMIRPS SCDPIM

Working collaboratively to reduce or prevent harm from medication use in Canada.

ismp CANADA

✓To date, over **200 standards, guidelines, and best practices** have been influenced by (e.g., reference) ISMP Canada incident analysis recommendations.

- All nurses (250,616) and pharmacists (6,375) working in accredited hospitals across Canada are required to follow the Medication Safety Standard and/or Required Organizational Practices (ROPs) developed with input from ISMP Canada.

- More than 374,000 reports of medication incidents have been received by ISMP Canada from practitioners, consumers and community pharmacies, to inform shared learning.

Another Example of Practice Change

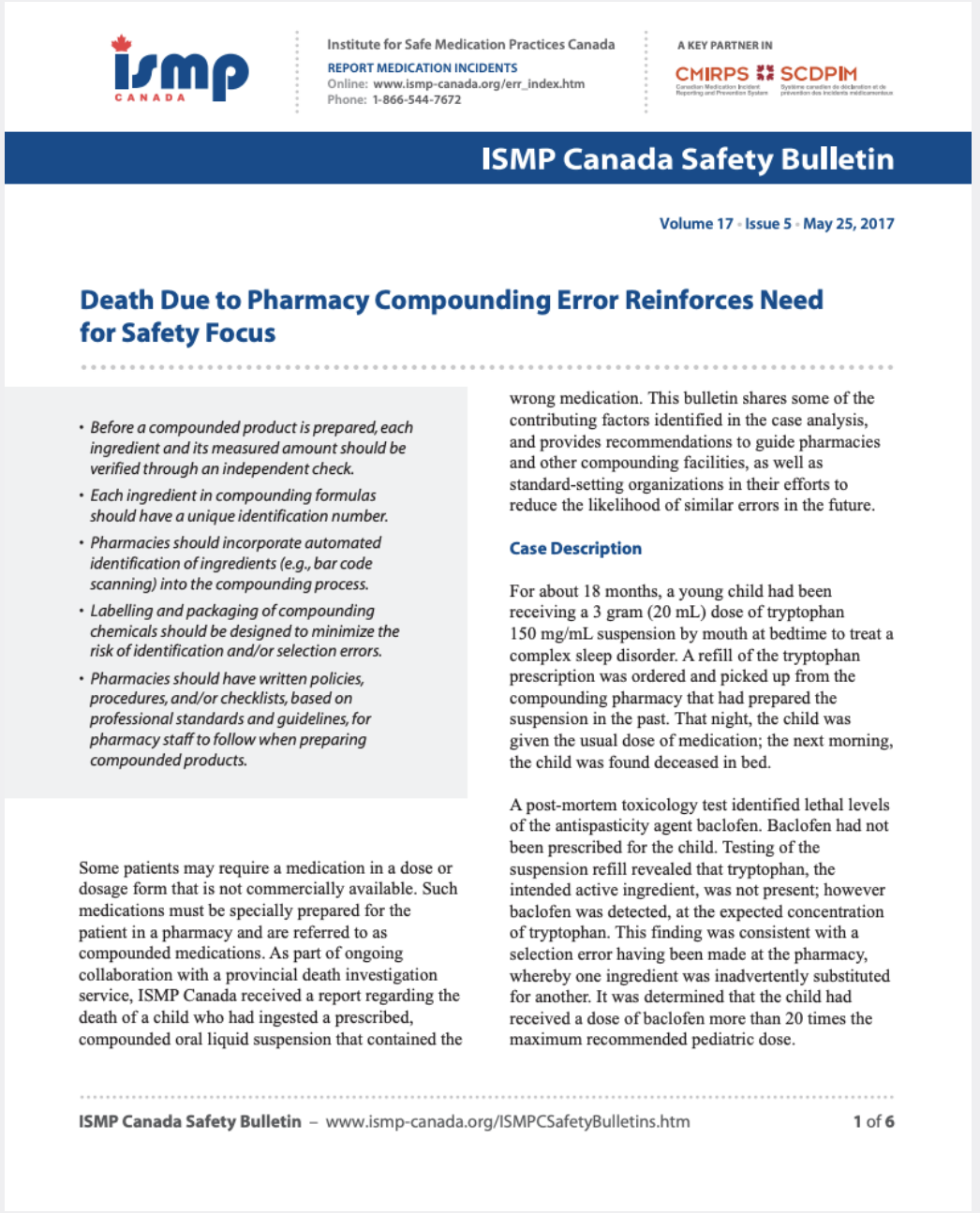
Reports of fatal errors lead to label changes

All products now have the warning "Paralyzing Agent" on the Ferrule/Cap

Local level reports that translated to safety improvement and impact.

Evaluation findings included a decrease in the number of reports of incidents involving inadvertent administration of neuromuscular blocking agents.

Safety Bulletins and Alerts



Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS SCDPIM

ISMP Canada Safety Bulletin

Volume 17 • Issue 5 • May 25, 2017

Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus

- *Before a compounded product is prepared, each ingredient and its measured amount should be verified through an independent check.*
- *Each ingredient in compounding formulas should have a unique identification number.*
- *Pharmacies should incorporate automated identification of ingredients (e.g., bar code scanning) into the compounding process.*
- *Labelling and packaging of compounding chemicals should be designed to minimize the risk of identification and/or selection errors.*
- *Pharmacies should have written policies, procedures, and/or checklists, based on professional standards and guidelines, for pharmacy staff to follow when preparing compounded products.*

Some patients may require a medication in a dose or dosage form that is not commercially available. Such medications must be specially prepared for the patient in a pharmacy and are referred to as compounded medications. As part of ongoing collaboration with a provincial death investigation service, ISMP Canada received a report regarding the death of a child who had ingested a prescribed, compounded oral liquid suspension that contained the wrong medication. This bulletin shares some of the contributing factors identified in the case analysis, and provides recommendations to guide pharmacies and other compounding facilities, as well as standard-setting organizations in their efforts to reduce the likelihood of similar errors in the future.

Case Description

For about 18 months, a young child had been receiving a 3 gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime to treat a complex sleep disorder. A refill of the tryptophan prescription was ordered and picked up from the compounding pharmacy that had prepared the suspension in the past. That night, the child was given the usual dose of medication; the next morning, the child was found deceased in bed.

A post-mortem toxicology test identified lethal levels of the antispasticity agent baclofen. Baclofen had not been prescribed for the child. Testing of the suspension refill revealed that tryptophan, the intended active ingredient, was not present; however baclofen was detected, at the expected concentration of tryptophan. This finding was consistent with a selection error having been made at the pharmacy, whereby one ingredient was inadvertently substituted for another. It was determined that the child had received a dose of baclofen more than 20 times the maximum recommended pediatric dose.

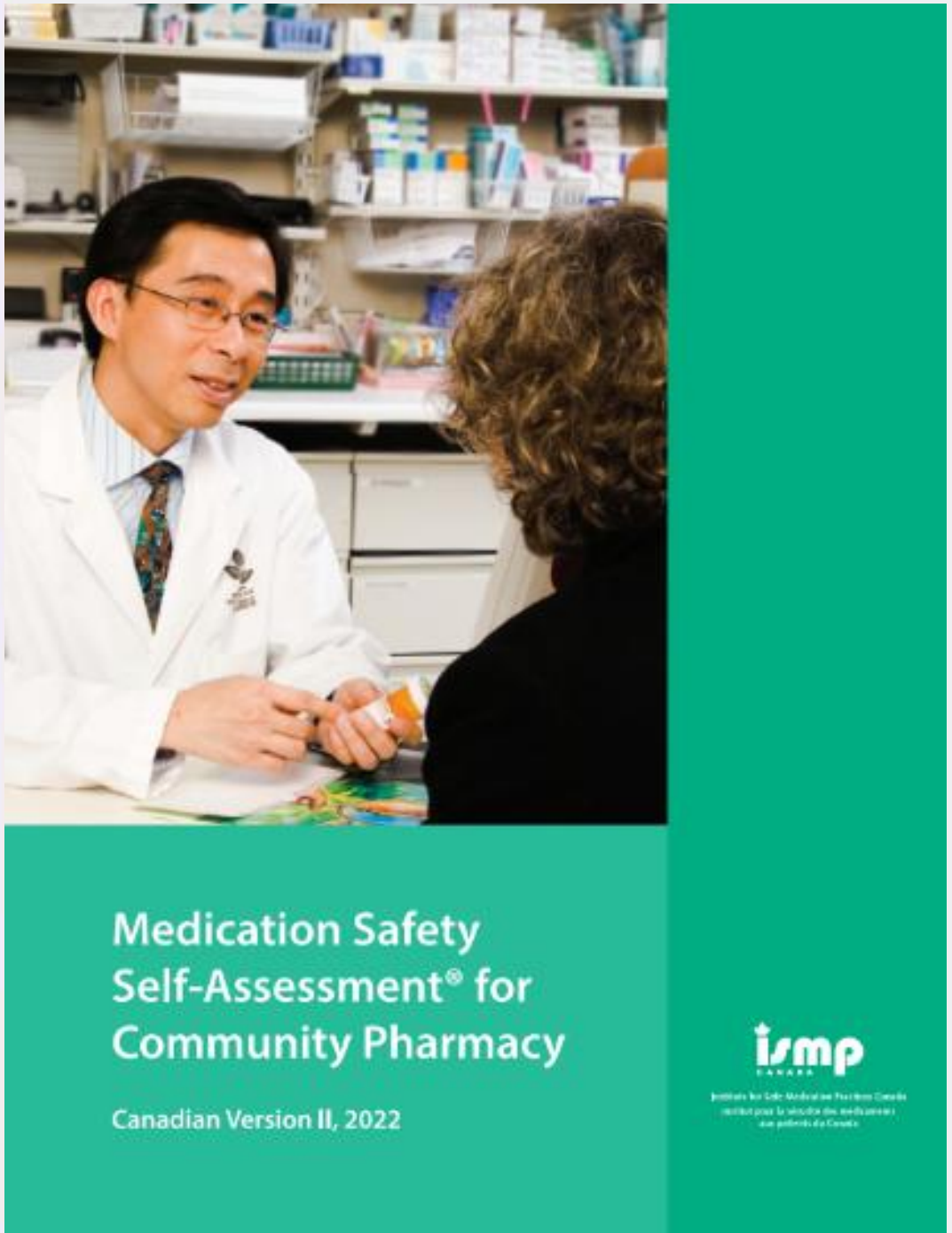
[Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus]

Continuous Improvement

[Safer Labelling of Repackaged Active Pharmaceutical Ingredients for Pharmacy Compounding]

[Tips for Parents When Medications Need to be Compounded]

Medication Safety Self Assessment

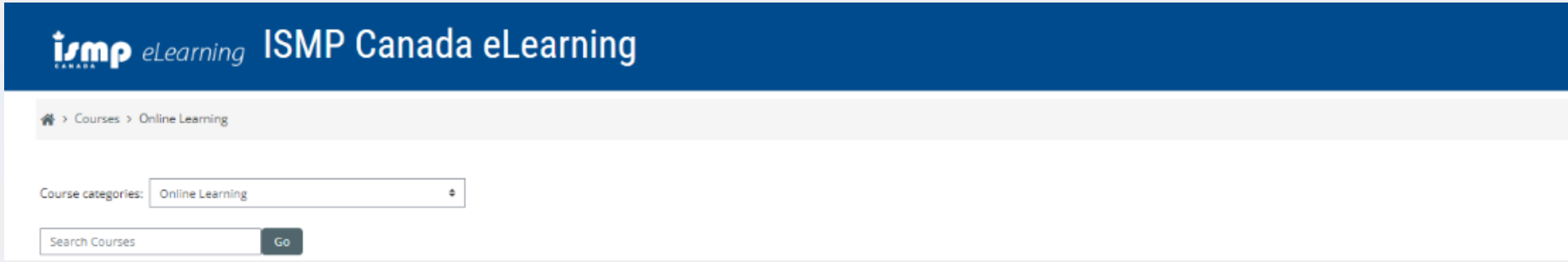


List provinces requiring MSSA

User Fee:

- Cost may include in pricing for platform provider
- Corporate pharmacy arrangements to purchase if platform provider does not provide
- Can be purchased as a separate tool from ISMP Canada for $150

eLearning and Online Modules



- **Keeping Pediatric Patients Safe: Pediatric Safety Considerations for Community Pharmacists**
- **Medication Safety Considerations for Compliance Packaging**
- **Preventing and Analyzing Medication Errors: A Primer for Community Pharmacies in Ontario**

Education - ISMP Canada

Live Virtual Workshops

Incident Analysis and Proactive Risk Assessment

▲ Overview

This virtual workshop will provide health care professionals with background theory and hands-on practice in incident analysis using Root Cause Analysis (RCA) and in proactive risk assessment using Failure Mode and Effects Analysis (FMEA).

5 upcoming dates - **Register**

- November 23 & 24, 2023
- December 16 & 17, 2023
- January 25 & 26, 2024
- February 24 & 25, 2024
- March 21 & 22, 2024

Multi-Incident Analysis and Medication Safety Culture Assessment

▲ Overview

This virtual workshop will provide participants with background theory and hands-on practice in using a multi-incident analysis to analyze a group of medication incidents that share a common topic on day 1 and introduce a novel tool called the Medication Safety Culture Indicator Matrix (MedSCIM) on day 2.

1 upcoming date - **Register**

- March 23 & 24, 2024

Medication Reconciliation and Best Possible Medication History

▲ Overview

This 1-day live facilitated virtual workshop teaches health care professionals the fundamentals of medication reconciliation (MedRec) and Best Possible Medication History (BPMH) while providing hands-on practice with case scenarios on how to conduct in-person and virtual medication history interviews.

2 upcoming dates - **Register**

- November 17, 2023
- March 2, 2024

Attachment 2



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ

Overview of the Patient Safety and Quality Improvement Act of 2005 (PSQIA), AHRQ's Patient Safety Organizations (PSO) Program, and Common Formats

Andrea Timashenka, JD
Director, PSO Division
Center for Quality Improvement and Patient Safety
January 2024

What Are the Most Relevant Authorities for the PSO Program?

- Patient Safety and Quality Improvement Act of 2005 (PSQIA)
  - Signed into law July 29, 2005
- Notice of Proposed Rulemaking
  - Published February 12, 2008
- Final Rule (Patient Safety Rule)
  - Published November 21, 2008;
  - Effective January 19, 2009

Where Did the Idea for the PSQIA Originate?

- To Err Is Human:
  - Committee believed there is value in both mandatory and voluntary reporting systems.
    - Mandatory systems: should focus on top tier of triangle. Essential for public accountability.
    - Voluntary systems: should address bottom tier and can result in information that will impact patient safety and can be widely disseminated. These reports and analyses should be protected.

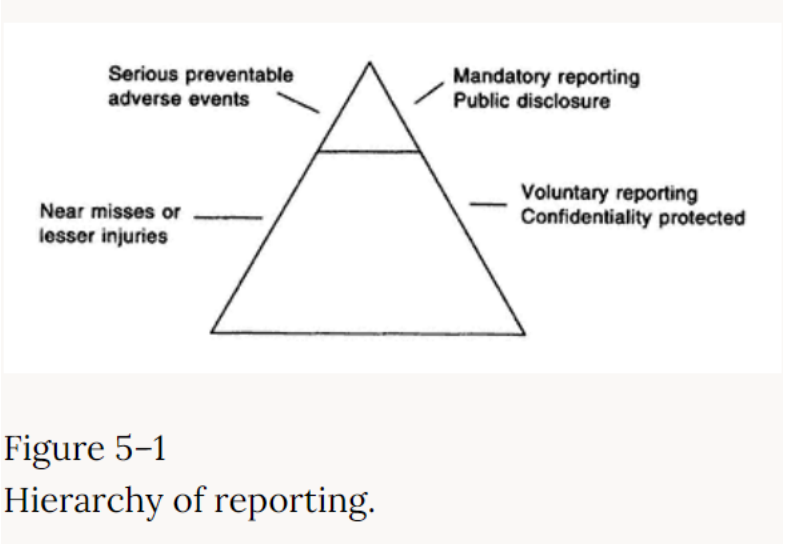


Figure 5–1
Hierarchy of reporting.

Where Did the Idea for the PSQIA Originate?

- More from To Err Is Human:
  - Committee recommended that Congress "pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality."
  - Committee recognized that existing state peer review laws, "vary considerably in their reach and strength."
  - Committee concluded that a "more conducive legal environment is needed to encourage health care professionals and organizations to identify, analyze, and prevent errors without increasing the threat of litigation and without compromising patients' legal rights."

PSQIA as a National Learning System

What does AHRQ's PSO Program do?

- Implements the Patient Safety and Quality Improvement Act of 2005 (PSQIA), including:
  - Conducting program operations and regulating PSOs
    - Certifying and listing PSOs (and "de-listing" PSOs, as applicable)
    - Conducting regulatory compliance assessments
    - Ensuring compliance with applicable requirements throughout the three-year period of listing
  - Developing Common Formats to promote standardized reporting and measurement
  - Maintaining the Network of Patient Safety Databases (NPSD)
  - Conducting technical assistance and preparing educational materials for PSOs, prospective PSOs, healthcare providers and the general public

What Legal Protections Are Provided Under the PSQIA?

- The PSQIA provides **broad confidentiality and privilege protections** (inability to introduce the protected information in a legal proceeding).
- Benefits of the PSQIA protections:
  - **Nationwide and uniform.** Apply in all U.S. states and territories, and across state lines.
  - **Not limited to the peer review process.** Can apply to a wide range of patient safety activities.
  - **Allows for shared learning.** For example, a healthcare system can pool data and share experiences across facilities and clinicians.
  - **Backed by penalties.** The PSQIA imposes significant monetary penalties for violations of the confidentiality provisions.

What is NOT Protected Under the PSQIA?

- The definition of PSWP excludes:
  - Patient's medical record, billing and discharge information;
  - Any other original patient or provider information;
  - Information collected, maintained, or developed separately, or exists separately from a patient safety evaluation system (PSES)
    - PSES: means the collection, management, or analysis of information for reporting to or by a PSO.

What is Protected Under the PSQIA?

- Information that meets the definition of "**patient safety work product**" (PSWP). It can be developed by the provider or PSO.

- The PSWP definition includes (but is not limited to):
  - Information (any data, reports, records, analyses, statements, etc.) that
    - Could improve patient safety, healthcare quality, or healthcare outcomes and which
    - The provider assembles or develops for reporting to a PSO and are reported to a PSO

Who Works with PSOs?

Under the PSQIA's implementing regulation, providers include:

- **All types** of **individuals and entities** licensed or otherwise authorized under State law to provide healthcare services can work with a PSO.
  - For example: hospitals, nursing homes, pharmacies, physicians, nurse practitioners, etc.

- Also,
  - government organizations that deliver health care, and
  - parent organizations* of licensed provider entities and government organizations that deliver health care.

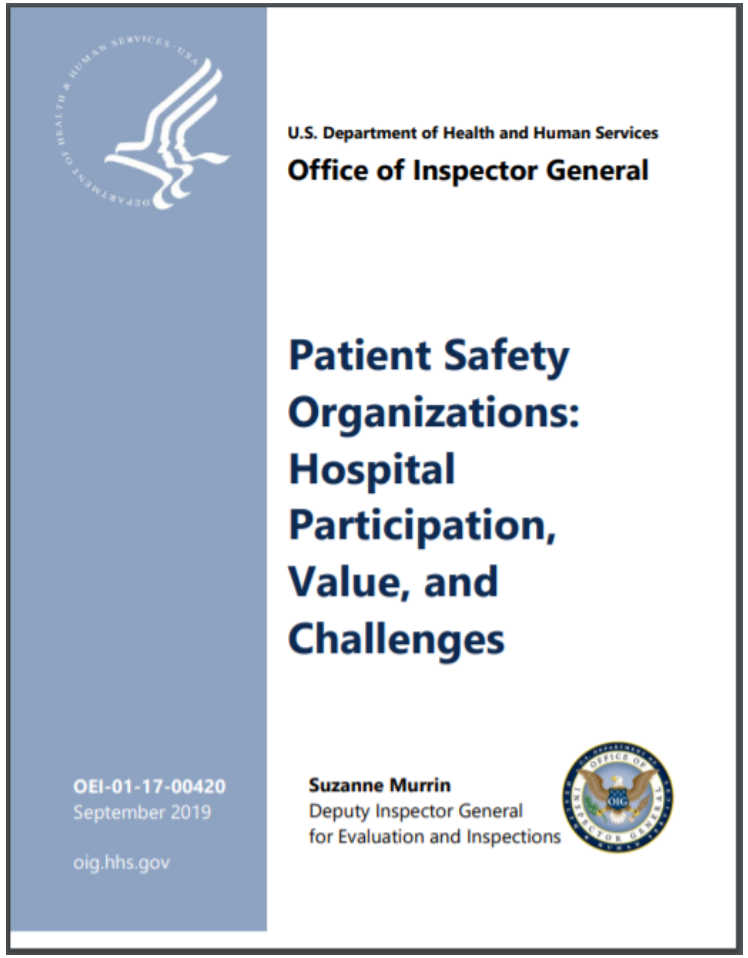
*See Patient Safety Rule at 42 C.F.R. §3.20 for definition of parent organization.

Working with a PSO is Valuable to Hospitals

- According to a 2018 survey conducted by HHS' Office of the Inspector General (OIG), 59% of general acute-care hospitals participating in Medicare work with a PSO.

- The OIG found that among hospitals that work with a PSO:
  - **97%** find it **valuable**
  - **80%** found the PSO's feedback and analysis **helped prevent future patient safety events**

OIG Report: *Patient Safety Organizations: Hospital Participation, Value, and Challenges*



More about the Common Formats

- Common Formats are a set of standardized definitions and formats that make it possible to collect, aggregate, and analyze uniformly structured information about patient safety for local, regional, and national learning.
- While anyone may use the Common Formats, the PSQIA protections only apply to information created as patient safety work product by providers working with PSOs.

Common Formats

- Active versions of CFERs
  - CFER – Hospital two versions active for reporting:
    - Version 1.2
    - Version 2.0
  - CFER – Nursing Home version 1.0
  - CFER – Community Pharmacy version 1.0
  - CFER – Diagnostic Safety version 1.0

- Common Formats for Surveillance
  - One version in development - Hospital version 0.3 beta

CFER – Community Pharmacies version 1.0

- The CFER-CP V1.0 module is designed for use in the community pharmacy environment to gain enhanced understanding about the circumstances surrounding patient safety data in the community pharmacy setting. This module is self-contained, covering everything necessary to report patient safety data in the Community Pharmacy event-specific category.

AHRQ Common Formats for Event Reporting – Community Pharmacy Version 1.0

Event Description

COMMUNITY PHARMACY

1.0 Definition of Event

A medication event involves one or more drugs, biological products, nutritional products, or medical foods.

1.1 Drugs/biologics

1.1.1 Prescription

1.1.2 Over-the-counter

1.1.3 Compounded preparations

1.1.4 Vaccines

1.2 Nutritional products/foods

1.2.1 Dietary supplements (other than vitamins or minerals)

1.2.2 Vitamins or minerals

1.2.3 Enteral nutritional products

1.2.4 Medical foods (dietary management of diseases or conditions)

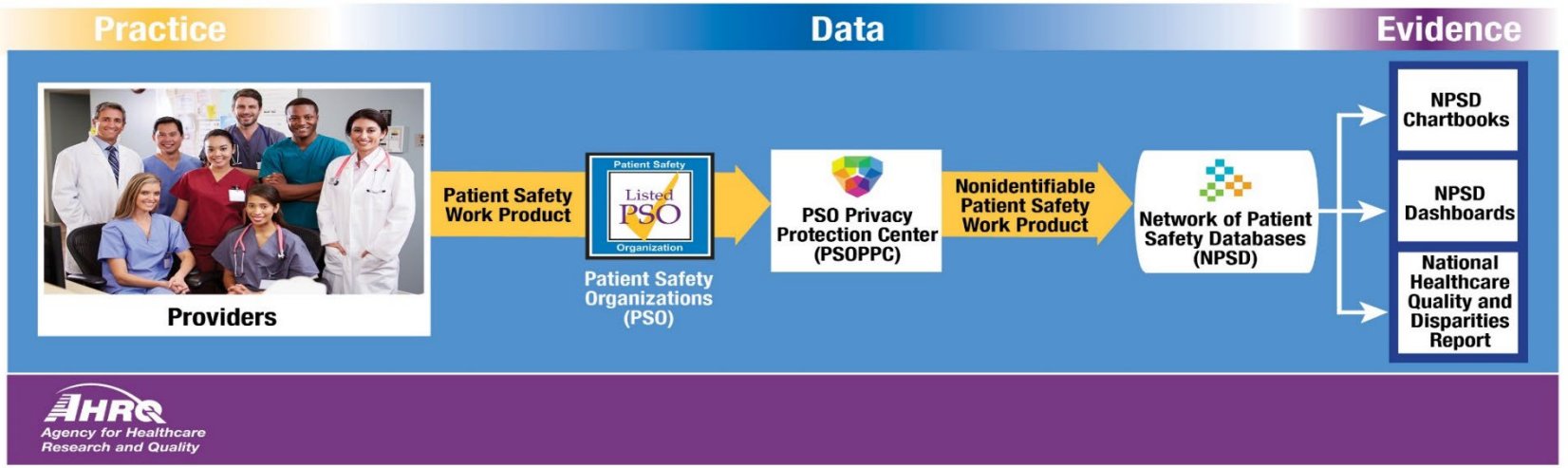
https://www.psoppc.org/psoppc_web/publicpages/commonFormatsCPV1.0

National Data Systems Related to the PSO Program

- Building national data systems to improve patient safety:
  - **NPSD**: an interactive, evidence-based management resource of patient safety concerns for the purpose of learning how to mitigate patient safety risks and reduce harm across healthcare settings nationally
    - As of September 2023, contains more than 2.6 million reports submitted in Common Formats for Event Reporting - Hospitals
  - **Quality and Safety Review System**: a denominator-driven, chart review-based system for in-patient patient safety events, built upon the Common Formats for Surveillance, that generates adverse event rates and trend performance over time. Replaced the Medicare Patient Safety Monitoring System.

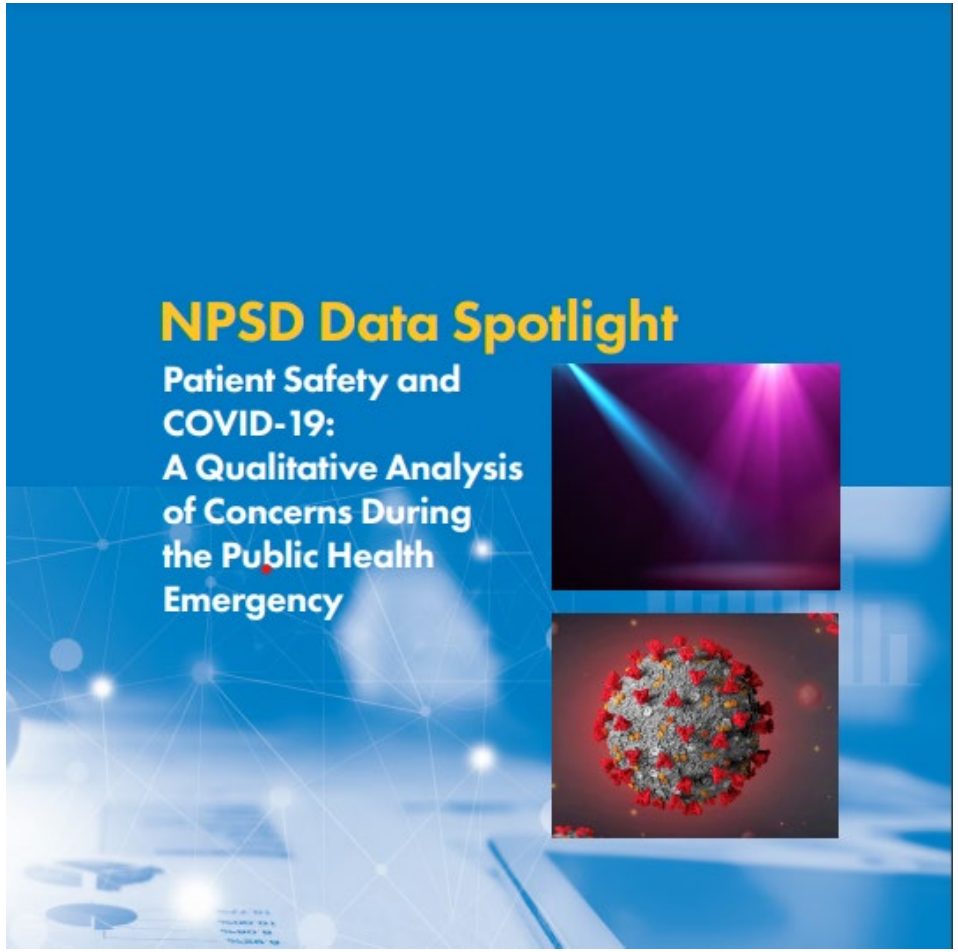
Data Flow Under the PSQIA

Network of Patient Safety Databases (NPSD) Data Flow



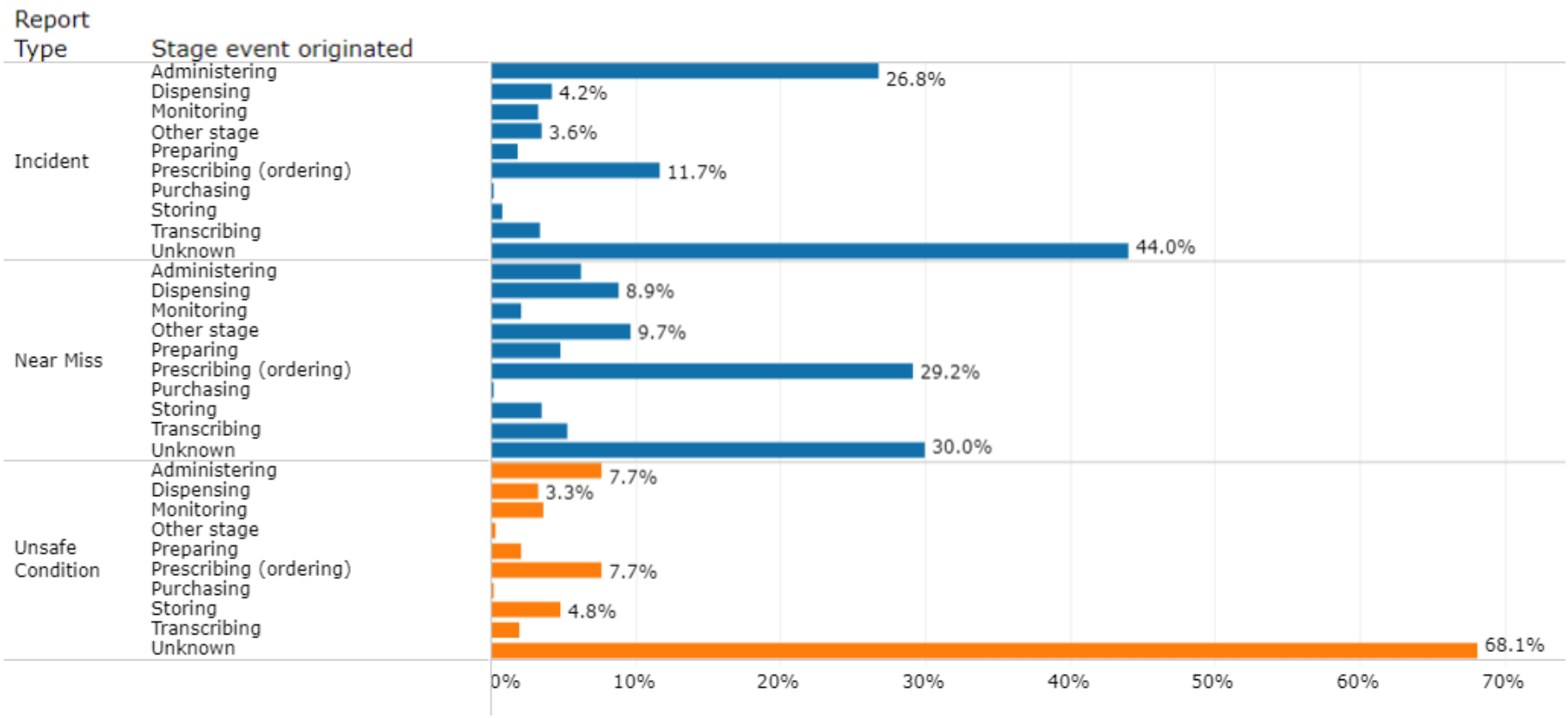
NPSD

- The NPSD makes available to the public only non-identifiable data as required by statute.
  - Data is aggregated, summary-level Patient Safety Event data
  - Does not make available to the public any PSO-level or record-level data on patient safety events
- Data presented in interactive Dashboards, Chartbooks, and Data Spotlight Reports.



NPSD Dashboards – 2022 Medications Supplement

Figure: Stage Event Originated by Report Type in CFER-H V1.2

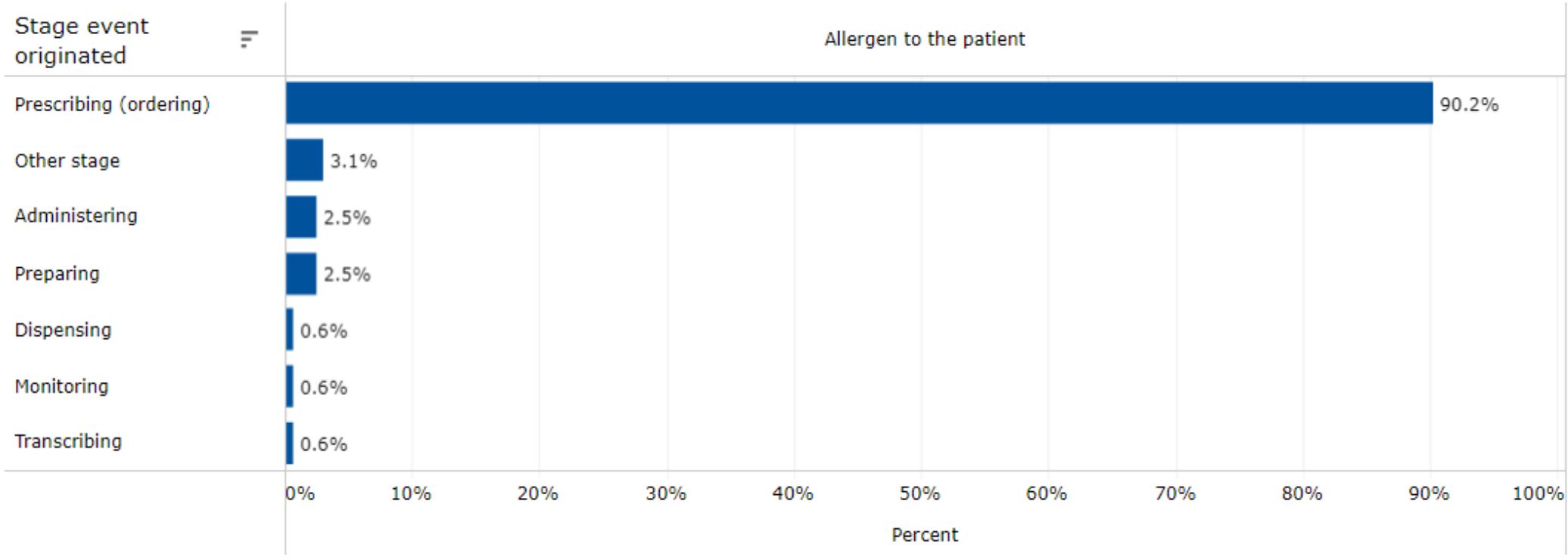


https://www.ahrq.gov/npsd/data/dashboard/medication-supplement.html

NPSD Dashboards – 2022 Medications Supplement

Distribution of Event Originated within Incorrect Action

Figure: Stage Event Originated by Incorrect Action in CFER-H V1.2



https://www.ahrq.gov/npsd/data/dashboard/medication-supplement.html

Questions?

Attachment 3

BUSINESS SERVICES
OFFICE/CONTRACTS
AND
PROCUREMENT

REQUEST FOR PROPOSAL

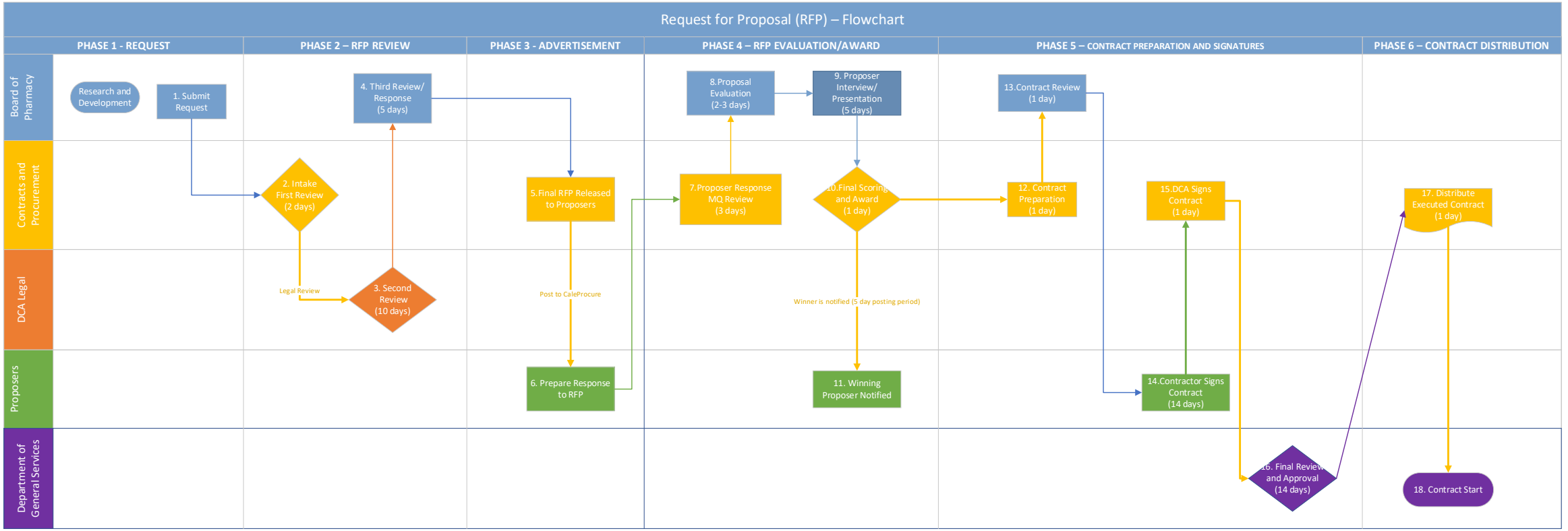
REQUEST FOR PROPOSAL

- Introduction
- Phase 1 - Request
- Phase 2 – RFP Review
- Phase 3 – Advertisement Period
- Phase 4 – RFP Evaluation/Award
- Phase 5 – Contract Preparation and Approvals
- Phase 6 – Contract Distribution
- Summary

INTRODUCTION

- Request for Proposal (RFP) is the solicitation method used to secure complex services calling for technical and/or professional skills and expertise.
- In an RFP, the department outlines requirements such as, administrative/technical specifications, evaluation methodology, bid preparation instructions and contract language. Proposers are responsible to responding to the requirements and how they intend to perform the work
- The estimated turnaround time for an RFP can vary between 3-9 months depending on the complexity of services and/or the requirements of the RFP.

RFP OVERVIEW

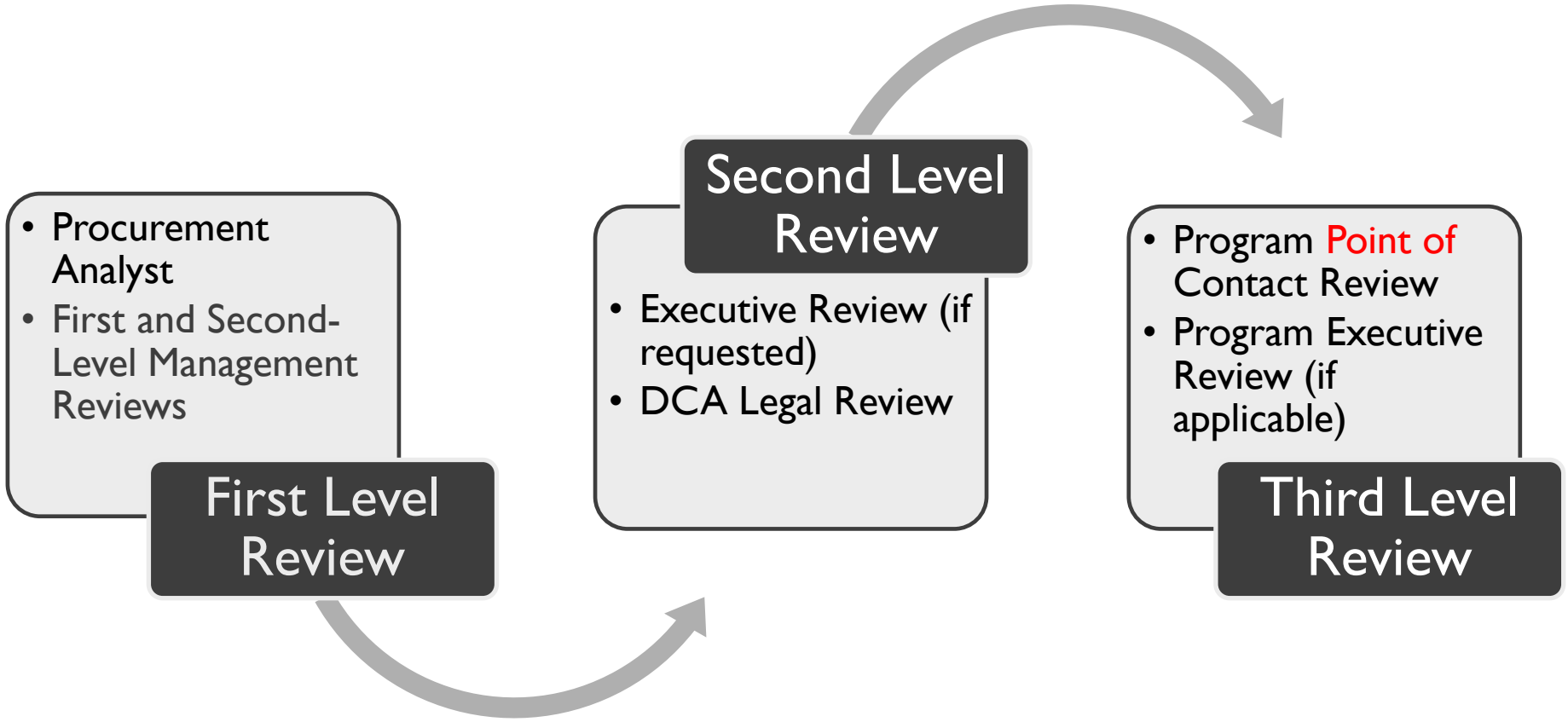


PHASE 1 - REQUEST

- **Research and Development**
  - Requestor is responsible for the following:
    - Identify the service need
    - Research vendors
    - Schedule a pre-solicitation meeting with Contracts and Procurement Management
- **Prepare the request by completing the following:**
  - BSO-47
  - RFP Template
    - Contact BSO Admin (bsoadmin@dca.ca.gov) for the template
    - Develop evaluation criteria and scoring matrix for interviews or presentations

- **Resources**
  - Vendor Search (Cal-eProcure): https://caleprocure.ca.gov/pages/LPASearch/lpa-search.aspx
  - Contract Search (Cal-eProcure): https://suppliers.fiscal.ca.gov/psc/psfpd1/SUPPLIER

PHASE 2 – RFP REVIEW



PHASE 3 – ADVERTISEMENT PERIOD

- **Procurement Analyst**
  - Advertise the RFP on CaleProcure
  - Ad will be active for at least 30 business days
    - 60 – 180 days is recommended for services requiring highly specialized skills
  - Conduct research and send RFP to three vendors
  - Coordinates the Question-and-Answer Period*
- **Vendors**
  - Develop RFP response
  - Submit questions/response to Procurement Analyst

*Question and Answer Period

- Allows for Vendors to request clarification on the RFP
- Provides DCA an opportunity to make non-material changes to the RFP through an Addendum

PHASE 4 – RFP EVALUATION/AWARD CONT.

- **Procurement Analyst – Minimum Qualification Review**
  - Conducts initial review of proposals
  - Determine pass/fail based on established criteria/requirements
  - Analyst confirms receipt of all required documentation
- **Program Contact – Proposal Evaluation**
  - Coordinate the evaluation panel to score proposals that meet the minimum qualifications
  - Panel must have a minimum of three panel members
  - Panel will evaluate and score the proposals based on the criteria outlined in RFP
  - Proposals that score at or above the stated cut-off point will move on to the interview phase
- **Program Contact – Interview/Presentation**
  - Program will coordinate the interview or presentations of vendors that passed the minimum qualification and proposal evaluations
  - Interviews or Presentations are conducted during a one-week period
  - Interviewed or Presentations are scored based on the criteria outlined in the RFP

PHASE 5 – CONTRACT PREPARATION AND APPROVALS

- **Procurement Analyst**
  - Prepares contract documents
    - Includes all required forms and exhibits
    - Sends final contract to Vendor for signature
    - Routes contract for DCA signatures
    - Submits to Department of General Services (DGS) for final approval
- **Program Contact**
  - Approves final contract before contract is sent to the vendor
- Vendor
  - Signs contract and returns to DCA

PHASE 6 – CONTRACT DISTRIBUTION

- **Procurement Analyst**
  - Finalizes and executes contract
  - Sends final contract to all parties
- **Program Contact**
  - Familiarize themselves with contract
  - Can engage with Vendor
  - Contract begins

SUMMARY AND CONTACTS

- **The RFP process consists of six phases**
- **Overall processing time from beginning to contract execution is 134 days (assuming a 60-day advertisement period)**
- **Contracts and Procurement Contacts (in priority)**
  - **Miriam Lopez, SSM II – Miriam.lopez@dca.ca.gov, (916) 659-8795**
  - **Jared True, SSM III, Jared.True@dca.ca.gov, (279) 278-5824**
  - **Mechelle Shultz, SSM I, Mechelle.Schultz@dca.ca.gov, (279) 278-5820**

Attachment 4

AQIPS ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

Patient Safety Organizations and Healthcare Providers Advancing Patient Safety

TRANSMITTED VIA ELECTRONIC MAIL

Chairperson Seung Oh

Re: Implementation of 4113.1 of AB 1296

Dear Chairperson Seung Oh:

The Alliance for Quality Improvement and Patient Safety (AQIPS) appreciates the opportunity to submit comments on the implementation of Section 4113.1 of AB 1286 Pharmacy. AQIPS is a not-for-profit, national professional association for Patient Safety Organizations and their health care providers, including pharmacies and pharmacists, and other providers in California and throughout the United States. As having expertise and significant experience in interpreting the Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299b-21 et seq.; the "Patient Safety Act"), AQIPS is uniquely qualified to provide the CA BOP with insight on how to implement section 4113.1 through a Patient Safety Organization (PSO). We anticipate that vast majority of the licensed pharmacies in California contract with a component or other PSO. As more fully discussed below, this memorandum highlights how:

1. Under 4113.1 and the Patient Safety Act, a licensed community pharmacy can report medication error Patient Safety Work Product (PSWP) to a PSO, which can transfer that medical error information to an entity approved by the board, subject to the provisions of the Patient Safety Act.
2. The selection of a PSO as the designated entity for reporting would best support this reporting process in compliance with the Patient Safety Act.
3. The consequences of not permitting PSOs to report PSWP to a PSO designated entity include increasing the burden on pharmacists.
4. The California Board of Pharmacy can leverage PSOs' role in continuous improvement in patient safety and quality by developing its reporting program in partnership with the community Pharmacy PSOs.

Under 4113.1 and the Patient Safety Act, a licensed community pharmacy may report Patient Safety work product to a PSO, which could transfer that PSWP to an entity approved by the board, subject to the provisions of the Patient Safety Act.

Under section 4113.1, a licensed community pharmacy shall report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board.

Chairperson Seung Oh
Re: Implementation of 4113.1 of AB 1296

Section 3.20 defined a Patient Safety Organization (PSO) as an entity or component thereof that is listed as a PSO by the Secretary in accordance with subpart B. Subpart B. Subpart B of the rule contains the requirements for a PSO. Section 3.102 requires, among other things, a PSO to conduct Patient Safety Activities as defined in section 3.20. Section 3.20 provides that Patient Safety Activities mean the following activities carried out by or on behalf of a PSO or provider:

(1) Efforts to improve patient safety and the quality of health care delivery;
(2) *The collection and analysis of patient safety work product*;
(3) The development and dissemination of information with respect to improving patient safety such as recommendations, protocols, or information regarding best practices;
(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
(6) The provision of appropriate security measures with respect to patient safety work product;
(7) The utilization of qualified staff; and
(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system (PSES). (42 U.S.C. 299b-21(5) (emphasis added)).

The collection of reports of medication errors by a pharmacy is an operation of the pharmacies PSES creates PSWP. Once reported to the PSO, the privilege protections and confidentiality obligations of patient safety work product cannot be waived but can be permissibly disclosed, while retaining their status as PSWP, subject to the same confidentiality obligations on the part of recipients (see 42 U.S.C. 299b-21(7)(a)(i)(I); 22(c) and (d)).

Nothing in the Patient Safety Act prevents a component PSO from providing protected PSWP to the BOP designated entity, subject to the provisions of the Patient Safety Act. The PSQIA permits PSOs to make disclosures of PSWP to an entity without waiving its protections. Under 42 U.S.C. 22(c)(1)(C), PSOs can make disclosures for patient safety activities to other entities if all providers agree. Under 4113.1, the pharmacies or their parent corporate entity would agree that the PSO can fulfill their reporting responsibility under section 4113.1. The reported PSWP could not include the pharmacy or individual healthcare providers' identifying information without their authorization; however, the reporting of PSWP without identifying the pharmacy or individual providers in consistent with the strong evidence demonstrating that a non-punitive, just culture approach to responding to errors and behaviors is the most effective in improving patient safety.

Nothing in Section 4113.1 prevents the entity approved by the board from accepting PSWP. Consistent the Patient Safety Act, section 4113.1 requires that the board may publish deidentified case summary information compiled from the data in the reports so long as deidentification is done in accordance with the requirements set forth in Section

164.514(b)(2) of Title 45 of the Code of Federal Regulations, and includes omitting the name of the reporting pharmacy (42 U.S.C. 299b-22(c)(1)(C)). Similarly, the other requirements in 4113.1 are consistent with the Patient Safety Act, for example, the reports are confidential and cannot be used for discipline (42 U.S.C. 299b-22(b)). The community pharmacy must maintain records demonstrating compliance with this requirement for three years and shall disclose these records immediately available at the request of an inspector (42 U.S.C. 299b-22(c)(1)(C)). Therefore, both laws can be read together and their requirements carried out without violating either law. Because the Patient Safety Act includes requirements to maintain the security and confidentiality of the PSWP and other reports, the designated entity should be a Patient Safety Organization.

The consequences of not permitting PSOs to report PSWP include increasing burden on pharmacies that could lead to under-reporting.

PSOs cannot accept non-PSWP reports from pharmacies for reporting to the state. Research and experience show that if healthcare providers must report to multiple sources, there is negative impact on the percentage of reports filed. Reports are a signal that require investigation of proprietary processes and without them it is difficult to make meaningful improvements. Additionally, the literature and experience show that mandatory reporting to outside organizations may reduce reporting by pharmacists in fear of reprisal. The resources required to report to multiple entities is an impediment to the continuous quality improvement process as pharmacies are already reporting PSWP to their component PSOs.

The California Board of Pharmacy can build on PSOs' success in reducing medical errors by developing its reporting program in partnership with the community Pharmacy PSOs.

The work of federally listed PSOs and healthcare providers to reduce medical errors and increase patient safety in various clinical settings and specialties is highly valued, successful, and thriving. "Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety Act of 2005," AHRQ, December 2021; Patient Safety Organizations: Hospital Participation, Value, and Challenges," OIG (OIE-01-17-00420 (2019)). The California Board of Pharmacy should build on this success by developing its reporting program in partnership with the Community Pharmacy PSOs.

Should you have any questions or require additional information, please contact me at pbinzer@allianceforqualityimprovement.org or 703.581.9285.

Sincerely yours,

Margaret C Binzer

Margaret Binzer
Executive Director and General Counsel
www.AQIPS.org

Attachment 5

Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which becomes effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a), (c), and (e)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity?

A: The Board is in the process of identifying an entity to receive AB 1286 medication error reports. Until the Board has approved the entity, medication errors do not need to be reported under BPC 4113.1. The Board reminds licensees, however, that provisions for documenting medication errors as established in California Code of Regulations (CCR), title 16, section 1711 (relating to quality assurance programs) remain effective. AB 1286 does not impact the quality assurance documentation requirements.

[Reference: BPC 4113.1(a); 16 CCR 1711]

4. Q: Given the delay in implementation for reporting medication errors under AB 1286, how will I know when the medication error reporting becomes effective?

A: The Board will use a variety of means to announce the approval of the entity and the implementation timeframe, including through the Board's subscriber alert system and posting information on its website.

Note: As a reminder, all licensees are required to enroll in the Board's subscriber alert system. Additional information is available here.

[Reference: BPC 4013]

5. **Q: I work in an outpatient hospital pharmacy. Do AB 1286's requirements for medication error reporting apply to our pharmacy?**

A: Yes. However, pursuant to subdivision (e) of BPC 4113.1, an outpatient hospital pharmacy shall not be required to report to the Board-approved entity a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to section 1279.1 of the Health and Safety Code (HSC). The State Department of Public Health may share any such report with the Board.

[Reference: BPC 4113.1(e)]

6. **Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?**

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

[Reference: BPC 4113.1]

7. **Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?**

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

Minimum Staffing Provisions

8. **Q: What minimum staffing requirements does AB 1286 establish?**

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.

- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, CLIA-waived tests, or any other ancillary services provided by law, this exemption does not apply.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6(a)]

Staffing Decisions

9. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

10. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

11. Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

12. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

13. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

14. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: –- PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,

- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

15. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

16. Q: What are the expanded duties pharmacy technicians may perform pursuant to AB 1286?

A: Effective January 1, 2024, qualified pharmacy technicians may perform the following duties under specified conditions:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as waived under CLIA
- Receive prescription transfers
- Accept clarification on prescriptions

[Reference: BPC 4115(b)]

17. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (*i.e.*, packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.
- The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b)(1)]

Unprofessional Conduct

18. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

19. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board online. Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

20. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

Surgical Clinic Provisions

21. Q: Under new requirements established by AB 1286, our surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form is currently being developed. Upon approval, the Board will release a subscriber alert and post the form on its website. The form will be available here.

[Reference: BPC 4192(b)]

22. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

23. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available here.

[Reference: BPC 4192(b), 4204(c)]

24. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee. It is recommended that licensees consider mailing the renewal application form, fee, and self-assessment form to the Board's office for handling, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

[Reference: BPC 4204(c))

December 21, 2023

Attachment 6

Mobile Units – Frequently Asked Questions

1. **Q: What is the difference between a mobile unit and a mobile pharmacy?**

   A: A mobile unit is operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority to provide prescription medication within its jurisdiction to individuals without fixed addresses, individuals living in county-owned or city-and-county-owned or operated housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

   In contrast, a mobile pharmacy is used temporarily when a pharmacy is destroyed or damaged, and the mobile pharmacy is necessary to protect the health and safety of the public, under specified conditions. The Board must approve the temporary use of a mobile pharmacy and the pharmacy operating the mobile pharmacy must provide the Board with records of the destruction of, or damage to, the pharmacy and an expected restoration date of the permanent pharmacy.

   A mobile pharmacy can also be employed during a declared federal, state, or local emergency in order to ensure the continuity of patient care, under specified conditions, including that the mobile pharmacy is located within the declared emergency area or affected areas.

   (BPC 4062(c), BPC 4110(c), BPC 4110.5)

2. **Q: How many mobile units may a county, city and county, or special hospital authority operate?**

   A: A county, city and county, or special hospital authority may operate one or more mobile units. The pharmacist-in-charge shall determine the number of mobile units that are appropriate for a particular pharmacy license.

   (BPC 4110.5)

3. **Q: What "special hospital authority" can operate a mobile unit?**

   A: The special hospital authorities that may operate a mobile unit are the Alameda Health System Hospital Authority described in Chapter 5 (commencing with Section 101850) of Part 4 of Division 101 of the Health and Safety Code, and the Kern County Hospital Authority described in Chapter 5.5 (commencing with Section 101852) of Part 4 of Division 101 of the Health and Safety Code.

   (BPC 4110.5, HSC 101850, HSC 101852)

4. **Q: How can a county, city and county, or special hospital authority notify the Board of their intent to operate a mobile unit?**

   A: A county, city and county, or special hospital authority shall notify the Board of its intention to operate a mobile unit as soon as possible, and no later than five business days after commencing operation of a mobile unit. To assist with notification requirements, the Board has developed a form that can be accessed here.

   (BPC 4110.5(f))

5. **Q: I am an independent retail pharmacy and would like to service my community by helping the homeless by providing better access in obtaining their medications. Can I operate a mobile unit?**

   A: No, only a county, city and county, or special hospital authority described in Chapter 5 (commencing with section 101850) or Chapter 5.5 (commencing with section 101852) of Part 4 of Division 101 of the Health and Safety Code may operate a mobile unit to provide prescription medications.

   (BPC 4110.5)

6. **Q: Can a clinic licensed by the Board pursuant to BPC 4180 qualify to operate a mobile unit?**

   A: No, a mobile unit can only be operated as an extension of a pharmacy license held by a county, city and county, or special hospital authority.

   (BPC 4110.5)

7. **Q: Our county operates a mobile unit. At the end of the day, can we park the mobile unit in a secured garage located where the pharmacy operating the mobile unit is located? Can we leave the drugs in the mobile unit if the garage has a security gate only accessible with a key fob by authorized personnel, the garage is well lit, and there is a security guard that patrols the area?**

   A: No, dangerous drugs must not be left in the mobile unit during the hours that the mobile unit is not in operation. The dangerous drugs must be returned to the licensed pharmacy.

   (BPC 4110.5(e))

8. **Q: At the end of the operational day, where can the mobile unit be parked?**

   A: Pharmacy law does not specify where the mobile unit is required to be parked. However, during the hours that the mobile unit is not in operation, dangerous drugs cannot be left in the mobile unit. Therefore, the Board recommends the mobile unit be parked at or close to the address of the licensed pharmacy since drugs are required to be stored and secured at the

licensed pharmacy operating the mobile unit.

(BPC 4110.5, 16 CCR 1714(b) and (d))

9. **Q: If a county, city and county, or special hospital authority plans to discontinue the use of a mobile unit, how should the Board be notified?**

   A: Notice of intention to discontinue operation of a mobile unit must be given to the Board , as soon as possible, and at least one business day before discontinuing operation of a mobile unit.-To assist with notification requirements, the Board has development a form that can be accessed here.

   (BPC 4110.5(f))

10. **Q: Does the mobile unit require the Notice to Consumer poster to be posted in public view?**

    A: Yes. The mobile unit operates as an extension of a pharmacy license held by the county, city and county, or special hospital authority. Pharmacy law requires every pharmacy to place the Notice to Consumer poster in a conspicuous place, physically access to a prescription drug consumer, so that the consumer can easily read it. The mobile unit must use the standardized poster provided or made available by the Board, unless the pharmacy has received prior approval of another format or display methodology from the Board. The mobile unit can also display the notice on a video screen located in a place conspicuous to and readable by consumers, subject to specified conditions.

    (BPC 4110.5, 16 CCR 1707.6)

11. **Q: Is the mobile unit required to have hot and cold running water?**

    A: Yes. The mobile unit operates as an extension of a pharmacy license held by the county, city and county, or special hospital authority. Therefore, the mobile unit must be equipped with a sink with hot and cold running water for pharmaceutical purposes.

    (BPC 4110.5, 16 CCR 1714(c))

12. **Q: Who can possess the keys to the mobile unit:**

    A: The mobile unit operates as an extension of a pharmacy license held by the county, city and county, or special hospital authority. When drugs are stored in the mobile unit, the key to the mobile unit is restricted to a pharmacist. The pharmacy owner (the county, city and county, or the special hospital authority) may possess a key to the mobile unit that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency, including fire, flood, or earthquake. The signature of the pharmacist-in-charge must be present in such a way that the pharmacist may readily determine whether the key was removed from the container.

    (BPC 4110.5, 16 CCR 1714(d) and (e))

13. **Q: Can a county pharmacy operate a mobile unit to assist the county's methadone program to dispense methadone to better serve the homeless population?**

    A: No. Methadone is classified as a Schedule II controlled substance and a mobile unit cannot carry or dispense controlled substances, except Schedule III, Schedule IV, or Schedule V controlled substances approved by the United States Food and Drug Administration (FDA) for the treatment of opioid use disorder.

    (BPC 4110.5(d), HSC 11055(c)(14))

14. **Q: What are the staffing limitations for a mobile unit?**

    A: A mobile unit operates as an extension of a pharmacy license held by the county, city and county, or special hospital authority. Therefore, if the pharmacy operating the mobile unit has a community pharmacy license (PHY or PHE) and only one pharmacist, it must have no more than one pharmacy technician performing the tasks specified in BPC 4115(a). The ratio of pharmacy technicians performing the tasks specified in BPC 4115(a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to BPC 4116 or 4117.

    (BPC 4110.5, BPC 4115(f)(1))

15. **Q: Can a pharmacist working on a mobile unit provide vaccine administration?**

    A: Yes. In addition to dispensing prescriptions, the pharmacist may perform activities consistent with Article 3 (commencing with section 4050) of the Business and Professions Code.

    (BPC 4110.5(b), BPC 4050-4068)

16. **Q: During the temporary absence of a pharmacist for their duty free breaks and meal periods, can the pharmacist leave the mobile unit, leaving ancillary staff in the mobile unit?**

    A: The decision to keep the mobile unit open during the temporary absence of the pharmacist for their duty fee breaks and meal periods resides with the pharmacist working in the mobile unit. The pharmacist may leave the mobile unit temporarily for breaks and meal periods without closing the mobile unit and removing ancillary staff if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in the pharmacist's absence.

    If the mobile unit remains open during any temporary absence of the pharmacist, no prescription medications may be provided to a patient or patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

    During the temporary absence of the pharmacist, an intern pharmacist may not

perform any discretionary duties nor otherwise act as a pharmacist. However, the intern pharmacist may perform non-discretionary tasks. Other ancillary staff may also continue to perform the non-discretionary duties authorized to them by Pharmacy Law.

(BPC 4110.5(a), 16 CCR 1714.1, 16 CCR 1793.2)

17. Q: Our mobile unit has very limited storage space. Where can a mobile unit store its records?

A: All records required by BPC 4081 and 4105 may be temporarily stored in the mobile unit while it is in operation. At the end of the day, when the mobile unit is not in operation, all records required by BPC 4081 and 4105 must be transferred and maintained on the licensed pharmacy premises that is operating the mobile unit.

(BPC 4110.5, BPC 4081, BPC 4105)

18. **Q: Are the prescription labels dispensed by the mobile unit required to have patient-centered labeling?**

    A: Yes, all prescription medication dispensed by the mobile unit must comply with all labeling requirements applicable to a California licensed pharmacy, including all the requirements for patient-centered labeling.

    (BPC 4076, BPC 4076.5, 16 CCR 1707.5)

19. **Q: Are pharmacists required to provide consultation for new prescriptions dispensed from the mobile unit?**

    A: Yes. The mobile unit is an extension of a pharmacy license held by a county, city and county, or special hospital authority. Therefore, the duty to consult applies to pharmacists working in mobile units in the same manner as it applies to pharmacists working in any other pharmacy.

    (BPC 4110.5, 16 CCR 1707.2)

20. **Q: If a physician is practicing in the mobile unit, writes a new prescription for the patient and consults the patient on how to take the new medication, is the pharmacist also required to provide consultation to the patient when the mobile unit dispenses the new prescription to the patient?**

    A: Yes, the pharmacist is still responsible to provide patient consultation pursuant to 16 CCR 1707.2.

    (BPC 4110.5, 16 CCR 1707.2)

21. **Q: Does a Board inspector have the authority to inspect a mobile unit?**
    A: Yes. Inspectors employed by the Board (or by the Division of Investigation of the Department of Consumer Affairs) may inspect during business hours all pharmacies or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.
    (BPC 4008)

22. **Q: When the mobile unit is in use, what operational standards and security measures apply to the mobile unit?**

    A: The mobile unit is operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority. Therefore, the mobile unit is required to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed. Further, the mobile unit and fixtures and equipment must be maintained in a clean and orderly condition, and the mobile unit must be dry, well-ventilated, free from rodents and insects, and properly lighted.

    Each pharmacist while on duty in the mobile unit is responsible for the security of prescription drugs in the mobile unit, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such

drugs and devices.

- (16 CCR 1714)

23. Q: Can the mobile unit carry and dispense controlled substances?

A: Mobile units can only carry and dispense Schedule III, Schedule IV, or Schedule V controlled substances approved by the FDA for the treatment of opioid use disorder.

(BPC 4110.5(d))

24. Q: How much buprenorphine, a Schedule III controlled substance approved by the FDA for the treatment of opioid use disorder, can be carried and stored on the mobile unit?

A: Any Schedule III, Schedule IV, or Schedule V controlled substance approved by the FDA for the treatment of opioid use disorder shall be carried in reasonable quantities based on prescription volume and stored securely in the mobile pharmacy unit.

(BPC 4110.5(d)(2))

25. Q: Can the mobile unit carry and dispense naltrexone?

A: Yes. Naltrexone is not a federally scheduled controlled substance. Currently, there is no prohibition, against a mobile unit carrying or dispensing this drug.

(BPC 4110.5)

26. Q: Does the mobile unit have to report the controlled substances dispensed for the treatment of opioid use disorder to CURES?

A: Yes.

(HSC 11165 (d))

Attachment 7

SURGICAL CLINIC SELF-ASSESSMENT FORM

Section 4192 of the Business and Professions Code requires the **consulting pharmacist** of a surgical clinic licensed under section 4190 of the Business and Professions Code to complete a self-assessment of the surgical clinic's compliance with federal and state laws.

The self-assessment must be completed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, and must assess the clinic's compliance with current laws and regulations, including information on compounding practices as specified on the most recent version of the surgical clinic Self-Assessment Form approved by the board and posted on its internet website.

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available at the surgical clinic. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment. Note: In addition to this form, the consulting pharmacist must certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article.

All references to the board are to the California Board of Pharmacy. All references to the California Code of Regulations (CCR) are to the board's regulations contained in Title 16 unless otherwise noted. Additionally, Business and Professions Code (BPC) are to Division 2 Healing Arts. Health and Safety Code (HSC) citations are contained in Division 10 Uniformed Controlled Substance Act. The Code of Federal Regulations (CFR) citations are to Title 21 Food and Drugs. United States Code (USC) citations are to Title 21 Food and Drugs.

Each self-assessment must be kept on file in the clinic for three years after it is performed.

Surgical Clinic Name: _____ _

Address: _____ Phone: _____

Fax: _____ Email: _____ Website: _____

Ownership: ☐ Sole Owner; ☐ Partnership; ☐ Corporation; ☐ LLC; ☐ Trust;

☐ Non-Licensed Owner; ☐ Other (please specify) _____

License #: _____ Exp. Date:_____ Other Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Weekdays _____ Sat._____ Sun. _____ 24 Hours _____

Professional Director: _____ License #:_____ Exp. Date: _____

Consulting Pharmacist: _____ RPH # _____ Exp. Date: _____

Check the type of Clinic, pursuant to BPC 4190:

Licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

An outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code.

An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (41 U.S.C. Section 1395 et seq.).

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. General Requirements

Yes	No	N/A	
☐	☐	☐	1.1 The clinic purchases or purchased drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. (BPC 4190[b].)
☐	☐	☐	1.2 A separate license has been and will be issued for each clinic location. (BPC 4190[b].)
☐	☐	☐	1.3 The clinic did or will notify the board of any change in the clinic's address on a form furnished by the board. (BPC 4190[b].)
☐	☐	☐	1.4 The clinic keeps records of the kind and amounts of drugs purchased, administered, and dispensed, and the records are available and maintained for a minimum of three years for inspection by authorized officers of the law or representatives of the board. (BPC 4190[b], 4081, 4105.)
☐	☐	☐	1.5 The drug distribution service of the clinic is limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. (BPC 4190[c])
☐	☐	☐	1.6 Drugs are not dispensed in an amount greater than that required to meet the patient's needs for 72 hours. (BPC 4190[c].)
☐	☐	☐	1.7 Drugs for administration are those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of the patient for their immediate needs. (BPC 4190[c].)
☐	☐	☐	1.8 Any proposed change in ownership or beneficial interest in the licensee will be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier. (BPC 4190[e].)

Yes No N/A

☐☐☐ 1.9 The clinic complies with all applicable laws and regulations of the State Department of Public Health and the board related to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. (BPC 4191[a].)

☐☐☐ 1.10 The clinic will or did notify the board within 30 days of any change in professional director on a form furnished by the board. (BPC4192[d].)

☐☐☐ 1.11 If the clinic has or had a temporary closure, the clinic will or did notify the board of any temporary closure as soon as any closure exceeds or exceeded three consecutive calendar days.. (CCR 1708.1.)

Note: A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless the closure exceeds four consecutive calendar days. (CCR 1708.1.)

☐☐☐ 1.12 The clinic joined the board's email notification list within 60 days of obtaining its license or at time of license renewal. (BPC 4013[a].)

☐☐☐ 1.13 The clinic updated its email address with the board's email notification list within 30 days of a change, if any, in the clinic's email address. (BPC 4013[b].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Duties of the Professional Director

Yes No N/A

☐☐☐ 2.1 The professional director is a physician and surgeon acting in their capacity as medical director or a dentist or podiatrist acting in their capacity as a director in a clinic where only dental or podiatric services are provided. (BPC 4192[c].)

☐☐☐ 2.2 There is a professional director that is responsible for the safe, orderly, and lawful provision of pharmacy services. (BPC 4192[a].)

☐☐☐ 2.3 In carrying out the professional director's responsibilities, a consulting pharmacist has been retained to approve the policies and procedures in conjunction with the professional director and administrator. (BPC 4192[a].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Duties of the Consulting Pharmacist

Yes No N/A

☐☐☐ 3.1 The consulting pharmacist visits the clinic regularly and at least quarterly. Nothing prohibits the consulting pharmacist from visiting more than quarterly to

review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures. (BPC 4192[a].)

Yes No N/A

☐☐☐ 3.2 The consulting pharmacist certifies in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of Article 14 for clinics. (BPC 4192[b].)

☐☐☐ 3.3 Each written certification by the consulting pharmacist is kept on file in the clinic for three years and includes recommended corrective actions, if appropriate. (BPC 4192[b].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Dangerous Drugs and Dangerous Device Inventory

Yes No N/A

☐☐☐ 4.1 Dangerous drugs and dangerous devices transferred, sold, or delivered to the clinic are transferred, sold, or delivered only to the clinic. (BPC 4059.5[b].)

☐☐☐ 4.2 The clinic receiving the delivery of dangerous drugs and dangerous devices signs for the receipt of the dangerous drugs and dangerous devices. (BPC 4059.5[d].)

☐☐☐ 4.3 All stock of any dangerous drugs or dangerous devices is, at all times during business hours, open for inspection by authorized officers of the law. (BPC 4080.)

☐☐☐ 4.4 The clinic keeps a current inventory as defined by Section 1718 of the board's regulations. (BPC 4081[a], CCR 1718.)

☐☐☐ 4.5 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the clinic is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i].)

☐☐☐ 4.6 The clinic captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii].)

☐☐☐ 4.7 The clinic is aware of the requirements of the Drug Quality and Security Act (DQSA), to have lot level traceability and , unit-level traceability. (21 USC 360eee-1[d][2], [g][1]f)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Controlled Substances

Yes No N/A

☐☐☐ 5.1 The clinic has obtained a registration from DEA to engage in the distribution and dispensing of controlled substances. (21 CFR 1301.11.)

☐☐☐ 5.2 No Schedule II controlled substances are dispensed in the clinic. (BPC 4194.)

☐☐☐ 5.3 Controlled substance inventories required by Title 21, Code of Federal Regulations Section 1304.04 are available for inspection upon request for at least three (3) years after the date of the inventory. (CCR 1718, 21 CFR 1304.11[c].)
Date completed:_____

☐☐☐ 5.4 Separate Schedule II records are maintained. This includes Schedule II invoices, U.S. official order forms, and inventory records. (21 CFR 1304.04[h].)

☐☐☐ 5.5 Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04[h][3].)

☐☐☐ 5.6 U.S. Official Order Form (DEA Form 222) or its electronic equivalent (CSOS) is utilized when ordering all Schedule II controlled substances. When Schedule II controlled substance orders are received by the clinic, for each item received, the date and quantity received is recorded.. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g].)

☐☐☐ 5.7 For each prescription for a federally Schedule II, III, IV or V controlled substance, the clinic reports the specified information to the Department of Justice or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the Department of Justice. (HSC 11165[d].)

☐☐☐ 5.8 The clinic or affected prescriber reports the theft or loss of prescription forms immediately to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. (HSC 11165.3.)

☐☐☐ 5.9 The clinic's prescribers authorized to prescribe, order, administer, or furnish a controlled substance consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient. (HSC 11165.4[a][1][A][i]).

☐☐☐ 5.10 The clinic took an initial inventory of all stocks of controlled substance on hand on the date the clinic first engaged in the distribution or dispensing of controlled substances. (21 CFR 1304.11[b]).

☐☐☐ 5.11 The clinic takes a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory can be taken on any date that is within two years of the previous biennial inventory date. (21 CFR 1304.11[c].)

☐☐☐ 5.12 The controlled substance inventory is taken either as of opening of business or as of the close of business on the inventory date and is indicated on the inventory. (21 CFR 1304.11[a].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Inventory Reconciliation

Yes No N/A

☐☐☐ 6.1 The clinic performs periodic inventory activities and prepares inventory reconciliation reports to detect and prevent the loss of federal controlled substances. (CCR 1715.65[a].)

☐☐☐ 6.2 Inventory reconciliation reports are prepared on an ongoing basis for federal Schedule II controlled substances, at least once every three months. (CCR 1715.65[a][1].)

☐☐☐ 6.3 Inventory reconciliation reports are prepared on an ongoing basis for the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months for the following: (CCR 1715.65[a][2])

6.3.1 Alprazolam, 1 milligram/unit

6.3.2 Alprazolam, 2 milligram/unit

6.3.3 Tramadol, 50 milligram/unit

6.3.4 Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.

☐☐☐ 6.4 Inventory reconciliation reports are prepared on an ongoing basis for any controlled substance not covered in 6.2 and 6.3. (CCR 1715.65[a][3][A])

☐☐☐ 6.4.1 The inventory reconciliation report is prepared for identified controlled substances lost no later than three months after discovery of the reportable loss of that controlled substance.

☐☐☐ 6.4.2 The report is completed if the loss is discovered either by the inventory activities required by 6.2 and 6.3, or in any other manner.

☐☐☐ 6.4.3 The report covers the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery.

☐☐☐ 6.4.3 At a minimum, the reportable loss or any pattern(s) of loss(es) identified by the consulting pharmacist or professional director, as defined by the clinic's policies and procedures.

☐☐☐ 6.4.4 There is an inventory reconciliation report for each pattern of loss identified.

☐☐☐ 6.5 Inventory activities for each controlled substance not covered in 6.2 and 6.3 are performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B].)

Note: Inventory activities means inventory and all other functions sufficient to identify loss of controlled substance. The functions sufficient to identify loss outside of the inventory reconciliation process must be identified with the pharmacy's policies and procedures. (CCR 1715.65[a][3][B].)

☐☐☐ 6.6 The consulting pharmacist reviews all the inventory activities performed and ~~,~~ ~~prepares~~ inventory reconciliation reports prepared, and establishes and maintains secured methods to prevent losses of federal controlled substances. (CCR 1715.65[b].)

☐☐☐ 6.7 The prepared inventory reconciliation report includes all of the following:

☐☐☐ 6.7.1 A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the clinic has an inventory. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required. (CCR 1715.65[c][1].)

☐☐☐ 6.7.2 The signature of the individual who performs the required inventory and date of the inventory or the report. (CCR 1715.65[c][1].)

☐☐☐ 6.7.3 A review of all acquisitions and dispositions of each federal controlled substance covered by the report since the last inventory reconciliation report covering the controlled substance. (CCR 1715.65[c][2].)

☐☐☐ 6.7.4 A comparison of 6.7.1 and 6.7.3 to determine if there are any variances. (CCR 1715.65[c][3].)

☐☐☐ 6.7.5 Identification of all records used to compile the report, which, along with the records themselves, are maintained in the clinic and are readily retrievable in the clinic for three years. (CCR 1715.65[c][4], 1715.65[e][2].)

☐☐☐ 6.8 The clinic submits to the board a report containing the identity, amount, and strength of each controlled substance lost, and the date of discovery of the loss, for all losses that have made the report necessary, no later than thirty days after the date of discovery. (CCR 1715.6[a], [b])

☐☐☐ 6.9 The clinic submits to the board a report for the discovery of the following controlled substance losses: (CCR 1715.6[a], [b])

☐☐☐ 6.9.1 Any loss of a controlled substance in one of the following categories that causes the aggregated amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: (CCR 1715.6[a][1][A]-[C])

6.9.1.1 For tablets, capsules or other oral medication, 99 dosage units.

6.9.1.2 For single-dose injectable medication, lozenges, film, such as oral, buccal and sublingual suppositories or patches, 10 dosage units.

6.9.1.3 For Injectable multi-dose unit, two or more multi-dose vials, infusion bags, or other containers.

☐☐☐ 6.9.2 Any loss of controlled substances, regardless of the amount, attributed to employee theft. (CCR 1715.6[a][2].)

☐☐☐ 6.10 The clinic notifies the DEA in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. (21 CFR 1301.74[c].)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

7. Drug Dispensing

Yes No N/A

☐☐☐ 7.1 The dispensing of drugs in the clinic is performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations. (BPC 4191[b].)

☐☐☐ 7.2 The clinic is aware that is it not eligible for any professional dispensing fee that is authorized under the Medi-Cal program (Chapter 7, commencing with Section 14000, of Part 3 of Division 9 of the Welfare and Institution Code). (BPC 4193)

☐☐☐ 7.3 The clinic does not offer drugs for sale or charge or bill for professional services for the dispensing or administering of drugs. (BPC 4193.)

☐☐☐ 7.4 Does the clinic have a licensed automated drug dispensing system (ADDS) placed and operated inside an enclosed building, with a premise address, at a location approved by the board that is owned/leased and operated by a pharmacy? If yes, (BPC 4427.1, 4427.3[b][3])

Name of Pharmacy: _____

ADDS license number:_____

☐☐☐ 7.5 Does the clinic have an unlicensed ADDS pursuant to Business and Professions Code section 4427.2(i) that is owned/leased and operated by a hospital pharmacy? If yes, (BPC 4427.1, 4427.2[i], 4427.3[b][3])

Name of Hospital Pharmacy:_____

Hospital Pharmacy license number: _____

☐☐☐ 7.6 The prescription labels contain all the required information. (BPC 4076.)

☐☐☐ 7.7 The prescription label is formatted in accordance with patient centered labeling requirements. (BPC 4076.5, CCR 1707.5.)

☐☐☐ 7.8 Whenever requested by a patient or patient's representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a].)

☐☐☐ 7.9 The clinic provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 7.10 Whenever an opioid prescription is dispensed to patient for outpatient use, the clinic prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

8. Drug Compounding

Yes No N/A

☐☐☐ 8.1 Does a pharmacy deliver compounded preparation to the clinic at which a patient receives health care services? (CCR 1713[b].) If yes:

Name of Pharmacy: _____

Pharmacy license number: _____

Sterile compounding license number: _____

Attach additional sheet if necessary.

☐☐☐ 8.2 Does the clinic purchase compounded drugs from a facility registered as an outsourcing facility with the federal Food and Drug Administration and concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution? (BPC 4129.) If yes:

Name of outsourcing facility: _____

Outsourcing Facility license #: _____

Attach additional sheet if necessary.

☐☐☐ 8.3 The clinic compounds for immediate use in compliance with the current United States Pharmacopeia Chapter 797 (USP 797). (USC 503A(b)(A)(i)(I))

☐☐☐ 8.4 The clinic compounds for future use in compliance with the current USP 797. (USC 503A(b)(A)(i)(I))

☐☐☐ 8.5 The clinic handles hazardous drugs in compliance with the current United State Pharmacopeia Chapter 800 (USP 800). (, USP 800)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

9. Policies and Procedures

Yes No N/A

☐☐☐ 9.1 The clinic has developed and approved policies and procedures to implement the laws and regulations by the consulting pharmacist, professional director, and the clinic administrator. (BPC 4191[a].)

☐☐☐ 9.2 The clinic has policies and procedures that were developed and approved by the consulting pharmacist, the professional director, and the clinic administrator to implement the laws and regulations: (BPC 4191[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

10. Record Keeping Requirements

Yes No N/A

☐☐☐ 10.1 Inventory reports and all records used to compile the report are readily retrievable in the clinic for three years. (CCR 1715.65[e][2].)

☐☐☐ 10.2 All records of manufacture and of sales, acquisition, receipt, shipment, or disposition of dangerous drugs and dangerous devices, at all times, during business hours are open for inspection by authorized officers of the law, and are preserved for at least three years from the date of making. This also includes the kind and amounts of drugs purchased, administered, and dispensed. (BPC 4081, BPC 4190[b].)

☐☐☐ 10.2.1 Purchase invoices for all prescription drugs. (BPC 4081[a])

☐☐☐ 10.2.2 Biennial controlled substance inventory. (21 CFR 1304.11[c], CCR 1718.)

☐☐☐ 10.2.3 U.S. Official Order Forms (DEA Form 222). (21 CFR 1305.13)

☐☐☐ 10.2.4 Power of Attorney for completion of DEA Forms 222. (21 CFR 1305.05)

☐☐☐ 10.2.5 Theft and loss reports (DEA Form 106). (BPC 4081, 21 CFR 1301.74[c])

☐☐☐ 10.2.6 Records documenting return of drugs to wholesaler or manufacturer. (BPC 4081[a].)

☐☐☐ 10.2.7 Records documenting transfers or sales to other clinics or reverse distributors. (BPC 4081, 4105, CCR 1718.)

☐☐☐ 10.2.8 Records of receipt and shipment. (BPC 4081.)

☐☐☐ 10.3 All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by the clinic is retained on the licensed premises in a readily retrievable form. (BPC 4105.)

☐☐☐ 10.4 Each completed quarterly written certification by the consulting pharmacist is kept on file in the clinic for three years. (BPC 4192[b])

☐☐☐ 10.5 Completed Surgical Clinic self-assessments signed under penalty of perjury are kept on file in the clinic for three years. (BPC 4192[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____

CONSULTING PHARMACIST CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have read, reviewed and completed the self-assessment of this clinic of which I am the Consulting Pharmacist. Any deficiency identified herein will be corrected by _____(date). The self-assessment was completed to the best of my professional ability and acknowledge failure to correct any deficiency identified could result in action by the board. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Consulting Pharmacist)

PROFESSIONAL DIRECTOR CERTIFICATION:

I, (please print) _____, Professional License # _____ hereby certify that I have read and reviewed the completed self-assessment of this clinic of which I am the Professional Director. Any deficiency identified herein will be corrected by _____(date). The self-assessment was completed to the best of my professional ability and acknowledge failure to correct any deficiency identified could result in action by the board. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that is provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Professional Director)

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

- Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
- HSC, Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
- USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control
- United States Pharmacopeia, Chapters 795, 797, 800, and 825

Attachment 8

DEPARTMENT OF CONSUMER AFFAIRS
Title 16. Board of Pharmacy

PROPOSED REGULATORY LANGUAGE
Self-Assessments

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Amend Section 1715 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new pharmacy permit has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
(3) There is a change in the licensed location of a pharmacy to a new address.
(c) A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using the components of Form 17M-13 (Rev. ~~1~~1/~~22~~24) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers shall assess compliance with current laws and regulations using the components of Form 17M-14 (Rev. ~~1~~1/~~22~~24) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference, and contain the following components:
(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including:
(A) Name and any license number(s) of the pharmacy and their expiration date(s);
(B) Address, phone number, ownership type, and website address, if applicable, of the pharmacy;

(C) Federal Drug Enforcement Agency (DEA) registration number, its expiration date, and date of most recent DEA inventory;
(D) Hours of operation of the pharmacy; and
(E) Accreditation by third party, if applicable, and dates of accreditation.
(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.
(3) The pharmacist-in-charge shall respond "yes", "no," or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials on the self-assessment.
(6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature on the self-assessment.
(7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature on the self-assessment.
(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

Credits
NOTE: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, Business and Professions Code.

Amend Section 1715 to Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1784. Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager.

(a) Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:
(1) A new license is issued.
(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.
(c) . Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 1/24~~12/21~~) which is hereby incorporated by reference. The form shall include the information required by this section.
(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:
(A) Name, license number of the premises, and the license expiration date;
(B) Address, phone number, website address, if applicable, and type of ownership;
(C) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;
(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and
(E) Hours of operation of the licensee.
(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.
(4) For each "no" response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.
(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.
(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:
(A) They have completed the self-assessment of the licensed premises for which they are responsible;
(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;
(C) They understand that all responses are subject to verification by the Board of Pharmacy; and
(D) The information provided in the self-assessment form is true and correct.
(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and understand that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.
(d) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.
(f) Any identified areas of noncompliance shall be corrected as specified in the certification.
Credits
NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.
HISTORY
1. New section filed 3-26-2007; operative 4-25-2007 (Register 2007, No. 13). For prior history, see Register 84, No. 10.
2. Change without regulatory effect amending subsection (c) filed 3-11-2009 pursuant to section 100, title 1, California Code of Regulations (Register 2009, No. 11).

3. Amendment of subsection (c) filed 9-19-2011; operative 10-19-2011 (Register 2011, No. 38).
4. Amendment of subsection (c) filed 4-20-2016; operative 4-20-2016 pursuant to Government Code section 11343.4(b)(3) (Register 2016, No. 17).
5. Amendment of section heading, section and NOTE filed 8-24-2022; operative 10-1-2022 (Register 2022, No. 34).
This database is current through 1/12/24 Register 2024, No. 2.
Cal. Admin. Code tit. 16, § 1784, 16 CA ADC § 1784

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legend: Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and dashed underline for added language.

COMMUNITY PHARMACY SELF-ASSESSMENT/

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 pursuant to 16 CCR 1715). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 pursuant to 16 CCR 1735.2[k]).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐

Non-Licensed Owner ☐ Other (please specify) ☐

License #: _____ Exp. Date:_____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding License# _____ Exp Date: _____

Licensed Remote Dispensing Site Pharmacy License # _____ Exp Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (if any): _____

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. APH=Advanced Practice Pharmacist, DEA=Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY SELF-ASSESSMENT /

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes	No	N/A	
☐	☐	☐	1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714[a])
☐	☐	☐	1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, CCR 1714[b], [d])
☐	☐	☐	1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714[b])
☐	☐	☐	1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714[c])
☐	☐	☐	1.5. The pharmacy sink has hot and cold running water. (CCR 1714[c])
☐	☐	☐	1.6. The pharmacy has a readily accessible restroom. (CCR 1714[g])
☐	☐	☐	1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also or instead display the notice on a video screen. Additional "Notice to Consumers" in languages other than English may also be posted. (BPC 4122[a], CCR 1707.6)
☐	☐	☐	1.8. "Point to Your Language" poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c])
☐	☐	☐	1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (BPC 680, BPC 4115.5[e], CCR 1793.7[c])
☐	☐	☐	1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (BPC 4032, 4058)
☐	☐	☐	1.11. Does the pharmacy compound sterile drugs? (If yes, complete the Compounding Self-Assessment as required by CCR 1735.2(k).)

Yes No N/A

☐☐☐ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects their ability to practice the profession or occupation authorized by their license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (BPC 4104[a])

☐☐☐ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (BPC 4104[b])

☐☐☐ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting their ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects their ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects their ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (BPC 4104[c])

☐☐☐ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.16. In addition to the email notification, the pharmacy has provided to the Board the electronic mail address and must notify the Board within 30 days of any change in the electronic mail address. (CCR 1704)

☐☐☐ 1.~~16~~17. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.~~17~~18. The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the customer the lower price. Additionally, the pharmacy submits the claim to the health care service plan or insurer. (BPC 4079[a], [b])

Yes No N/A

~~☐☐☐ 1.18. A pharmacy that dispenses controlled substances shall display safe storage products (a device made with the purpose of storing prescription medications with a locking or secure mechanism for access by the patient, i.e., medicine lock boxes, locking medicine cabinets, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists who owns 4 or less pharmacy. (BPC 4106.5[a], [b])~~

☐☐☐ 1.19. A community pharmacy does not require a pharmacist employee to engage in practice of pharmacy at any time the pharmacy is open to the public unless either another employee at the establishment is made available to assist the pharmacist at all times unless the pharmacy is exempted. (BPC 4113.5)

- ☐ 1.19.1. The pharmacy has designated the name(s) of personnel who will be available to assist the pharmacist; (CCR 1714.3[a][1])
- ☐ 1.19.2. Designated personnel are able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3, and is qualified to have access to controlled substances; (CCR 1714.3[a][2], [3])
- ☐ 1.19.3. Designated personnel respond and are able to assist the pharmacist within five minutes after the pharmacist's request; (CCR 1714.3[a][4])
- ☐ 1.19.4. The pharmacy has policies and procedures in compliance with CCR 1714.3; (CCR 1714.3[b])
- ☐ 1.19.5. All impacted pharmacy employees and designated persons have read and signed a copy of the policies and procedures. (CCR 1714.3[c])

☐☐☐ 1.20. The pharmacy has the capability to receive an electronic data transmission prescription on behalf of a patient. (BPC 688[b])

- ☐ 1.20.1. The pharmacy shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. (BPC 688[b][2])
- ☐ 1.20.2. The pharmacy's staff is aware they are not required to verify that a prescription falls under one of the exceptions and that they may continue to dispense medication from a legally valid written, oral or fax prescription. (BPC 688[i])
- ☐ 1.20.~~1~~3. For prescriptions for controlled substances, as defined by BPC section 4021 generation and transmission of the electronic data transmission prescription complies with Parts 1300, 1304, and 1311 of Title 21 of the Code of Federal Regulations. (BPC 688[c])
- ☐ 1.20.~~2~~4. At the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester, unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. (BPC 688[g]~~)~~, 21 CFR 1300, 1304,

1306, 1311) ~~Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law~~.

☐ 1.20.~~3~~5. If ~~the~~ pharmacy~~, or its~~ staff~~,~~ is aware that an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, pharmacy staff immediately notifies the prescribing health care practitioner. (BPC 688[h])

Yes No N/A

☐☐☐ 1.21. The pharmacy performs FDA approved or authorized tests that are classified as CLIA waived. (BPC 4119.10)

☐ 1.21.1. The pharmacy is appropriately licensed as a laboratory under Section 1265 of the Health and Safety Code. (BPC 4119.10[a])

CDPH (CLIA) Registration #: _____ Expiration: _____

☐ 1.21.2. The pharmacy maintains policies and procedures as specified in. (BPC 4119.10[b])

☐ 1.21.3. The tests are authorized to be administered by a pharmacist pursuant to BPC 4052.4(b)(1). (BPC 4119.10[c])

☐ 1.21.4. The pharmacist-in-charge reviews the policies and procedures annually, assesses compliance with its policies, documents corrective actions to be taken when noncompliance is found, and maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years. (BPC 4119.10[d])

☐ 1.21.5. The pharmacy maintains documentation related to performing tests, including the name of the pharmacist performing the test, the results of the test, and communication of results to the patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years. (BPC 4119.10[e])

☐☐☐ 1.22. If the pharmacy qualifies as a chain store as defined in BPC 4001, the chain community pharmacy does not establish a quota. (BPC 4113.7, BPC 4317)

☐☐☐ 1.23. The pharmacy must report to the board any disciplinary action taken by any government agency since its last license issuance or last renewal. (CCR 1702.5)

☐☐☐ 1.24. When the pharmacy temporarily closes, the pharmacy must notify the board of the temporary closure as soon as closure **exceeds three consecutive calendar days**. A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. (CCR 1708.1)

☐☐☐ 1.25. A chain community pharmacy shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services, unless the pharmacist on duty waives the requirement in writing during specified hours based on workload need; the pharmacy is open before 8:00am and after 7:00pm; or the pharmacy's average prescription volume per day is less than 75 prescriptions, for the past calendar year and the pharmacist is not expected to provide any ancillary services provided by law. (BPC 4113.6[a][1],[2],[3])

PIC Initials

Yes No N/A

☐☐☐ 1.26. Within a chain community pharmacy, where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message. (BPC 4113.6[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (BPC 4059.5[a], HSC 1120[a])

☐☐☐ 2.2. The pharmacy takes delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty ~~if~~ only when all of the following requirements are met: (BPC 4059.5[f])

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy; (BPC 4059.5[f][1])
- ☐ 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered; (BPC 4059.5[f][2])
- ☐ 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered; (BPC 4059.5[f][3])
- ☐ 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility; and (BPC 4059.5[f][4])
- ☐ 2.2.5. The agent delivering dangerous drugs and dangerous devices leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy is responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy is also responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. BPC 4059.5[f][5])

☐☐☐ 2.3. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])

☐☐☐ 2.4. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not

apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])

☐☐☐ 2.5. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (21 USC sections 331, 351, 352, BPC 4342, HSC 111255, 111335, CCR 1714[b], 22 CCR 70263[q])

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold, warehoused, distributed or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy, or manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5[b], 4169)

- ☐ 3.2.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.
- ☐ 3.2.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.
- ☐ 3.2.3. Are not expired.

☐☐☐ 3.3. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 3.4. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 3.5. The pharmacy is aware that pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023, unit-level traceability. (21 USC 360eee-1[d][2], [g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Voluntary Drug Repository and Distribution Program (HSC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

~~(If yes, complete Section 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)~~

☐ 4.1.1. The pharmacy that donates medications to or operates a voluntary county approved drug repository and distribution program meets all the requirements as specified in law. (HSC 150200, 150201, 150202, 150202.5, 150203, 150204, 150204.5, 150204.6, 150205, BPC 4169.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4113.6, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new license is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ 5.4. Is the PIC in charge of another pharmacy?

☐☐☐ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101[a], 4113[e~~d~~])

☐☐☐ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (BPC 1206.~~5~~6, 1209, 1265)

☐☐☐ 5.8. The PIC or pharmacist, if PIC is not available, may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation. (BPC 4113[c][2])

☐☐☐ 5.9. The PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the board is timely notified. (BPC 4113[d][1]

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. A pharmacist:

- ☐ transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
- ☐ administers drugs and biological products ordered by the prescriber; (BPC 4052[a][3])
- ☐ manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; (BPC 4052[a][7])
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
- ☐ provides professional information and participates in multidiscipline review of patient progress; (BPC 4052[a][9])
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations, HIV preexposure prophylaxis, HIV postexposure prophylaxis pursuant to a protocol; (BPC 4052 [a][10], 4052[a][11], 4052.01, 4052.02, 4052.03, 4052.3, 4052.8, 4052.9)
- ☐ dispenses aid-in-dying drugs; (HSC 443.5 [b][2])
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies; (BPC 4052 [a][12])
- ☐ initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority; and (BPC 4052 [a][13])
- ☐ provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law. (BPC 4052 [a][14])

Yes No N/A

☐☐☐ 6.2. In addition, a pharmacist:

- ☐ receives a new prescription order from the prescriber; (CCR 1793.1[a])
- ☐ consults with the patient; (BPC 4052[a][8], CCR 1707.2, CCR 1793.1[b])
- ☐ identifies, evaluates, and interprets a prescription; (CCR 1793.1[c])
- ☐ interprets the clinical data in a patient medication record; (CCR 1793.1[d])
- ☐ consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1[e])
- ☐ supervises the packaging of drugs; (CCR 1793.1[f])
- ☐ checks the packaging procedure and product upon completion; (CCR 1793.1[f])
- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e]) or
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (BPC 4052, 4052.02, 4052.03, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1[g])

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or a

provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (BPC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ 6.4. Pharmacists have obtained approval to access the CURES Prescription Drug Monitoring Program (PDMP). (HSC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraception only pursuant to the statewide protocol found in CCR 1746. (BPC 4052.3[b][1])

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (BPC 1206.6)

☐☐☐ 6.7. Only a pharmacist performs FDA-approved or authorized CLIA waived clinical laboratory tests as specified in law. ~~in BPC 4052.4.~~ (BPC 4052.4, BPC 1206.6, BPC 4119.10)

CDPH (CLIA) Registration #: _____ Expiration: _____

☐☐☐ 6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (BPC 4052[b])

☐☐☐ 6.9. ~~Effective July 1, 2022, a~~ A pharmacist who is authorized to initiate or adjust a Schedule II Controlled substance shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs. (BPC 4232.5[a])

☐☐☐ 6.10. All pharmacists have joined the board's email notification list. (BPC 4013)

☐☐☐ 6.11. Only prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in BPC 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. (BPC 4071.1)

☐☐☐ 6.12. A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification of medication chart order (BPC 4071.1[d][1], 4071.1[d][2][a]).

☐☐☐ 6.13. Until January 1, 2025, a pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2, the virus that cause COVID-19, , when the following are met: (BPC 4052.04 [a])

- ☐ 6.13.1. Prior to furnishing COVID-19 oral therapeutics pursuant to 4052.04(a), a pharmacist utilizes relevant and appropriate evidence-based clinical guidelines published by the federal Food and Drug Administration in providing these patient care services (BPC 4052.04[b]):
- ☐ 6.13.2. A pharmacist notifies the patient's primary care provider, enters the appropriate information in a patient record system shared with the primary care provider, or, if the patient does not have a primary care provider, provides the patient a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice (BPC 4052.04[c]):
- ☐ 6.13.3 A pharmacist documents the kind and amounts of COVID-19 oral therapeutics furnished pursuant to 4052(a), as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. These records shall be maintained for three years and shall be available for inspection by all properly authorized personnel of the board (BPC 4052.04[d])

☐☐☐ 6.14. A pharmacist shall submit proof satisfactory to the Board that they have successfully completed 30 hours of approved courses of continuing pharmacy education, including at least one hour of participation in a "cultural competency course," (as defined in BPC 4231) during the two years preceding the application for renewal. (BPC 4231, 4233, 4234, CCR 1732,1732.05, 1732.1, 1732.2, 1732.3, 1732.4, 1732.5, 1735.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 7.1. The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 7.1.1. Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a][1]-[3])
- ☐ 7.1.2. Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a][4])
- ☐ 7.1.3. Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[a][5], [b])
- ☐ 7.1.4. Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[a][5], [b])
- ☐ 7.1.5. Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])

☐ 7.1.6. Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist performs the functions of a pharmacist only under the direct supervision of a pharmacist. The pharmacist supervises no more than **two interns** at any one time. (BPC 4114, 4023.5, CCR 1726)

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], CCR 1726)

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty-free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 8.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. Pharmacy technicians only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician performing packaging, manipulative, repetitive, or other nondiscretionary tasks. If a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, a second pharmacy technician shall be assisting a pharmacist with performing the tasks as defined in BPC 4115(a). For each additional pharmacist

present, the ratio may not exceed 2 technicians for each additional pharmacist. (BPC 4038, 4115[a], [gf][1], CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies them as a pharmacy technician or pharmacy technician trainee. (BPC 680[a], 4115.5[e], CCR 1793.7[c])

Yes No N/A

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[d])

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 140 hours. (BPC 4115.5)

☐☐☐ 9.6. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

☐☐☐ 9.7. A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician. A certification only is not equivalent to being licensed by the board as a pharmacy technician. (BPC 4115[f])

☐☐☐ 9.8. A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])

☐ 9.8.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist; (BPC 4115[b][1][A])

☐ 9.8.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board; (BPC 4115[b][1][B], BPC 4202[a][4])

☐ 9.8.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C]; and

☐ 9.8.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

☐☐☐ 9.9. A pharmacy technician submits proof satisfactory to the Board of successfully completing at least one hour of participation in a "cultural competency course" (as defined in BPC 4231) during the two years preceding the application for renewal. (BPC 4202)

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request;
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of their professional judgment; and
- ☐ 11.1.5. all of the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

Yes No N/A

☐☐☐ 11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ 11.4. Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)

☐☐☐ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (BPC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (BPC 4070, CCR 1717[c])

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (BPC 4071)

☐☐☐ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717[c], 1712)

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (BPC 4040[c])

☐☐☐ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 2290.5, 2242, 2242.1, 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under HSC 11159.2 (terminally ill exemption), 11159.3 (declared emergency exemption), and 11167.5 (SNF, ICF, licensed home health agency and licensed hospice exemption), all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (HSC 11164[a], 11167.5, 11162.1, 11159.2, 11159.3)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR parts 1300, 1306, 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (BPC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐☐☐ 13.3. The expiration date~~s~~ of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐☐☐ 13.4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement

"generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076[a][1], CCR 1707.5[a][1], 1717[b][2])

☐☐☐ 13.5. Generic substitution is communicated to the patient. (BPC 4073)

☐☐☐ 13.6. When a biological product is substituted with an alternative biological product, all the requirements of BPC 4073.5 are met. (BPC 4073.5)

☐☐☐ 13.7. If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or the identity of the reviewing pharmacist is recorded in a computer system by a secure means. (BPC 4115, 4115.5[b][3], CCR 1793.7, CCR 1712)

☐☐☐ 13.8. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 13.9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717[a])

☐☐☐ 13.10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.12. Medication guides are provided on required medications. (21 CFR 208.24[e])

☐☐☐ 13.13. The pharmacy furnishes dangerous drugs in compliance with:

- ☐ BPC 4119(b) to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency. (BPC 4119)

- ☐ BPC 4126.5(a) only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.14. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076[a][11])

☐☐☐ 13.15. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐☐☐ 13.16. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (HSC 11200[b])

☐☐☐ 13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, psychotropic medications and self-administered hormonal contraception, under the following provisions: (BPC 4064.5)

- ☐ 13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (BPC 4064.5[a])
  - ☐ 13.17.1.1. The prescriber has not indicated “no change to quantity” or words of similar meaning; (BPC 4064.5[d])
  - ☐ 13.17.1.2. The patient has completed an initial 30 day supply; (BPC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90 day supply. BPC 4064.5[b])
  - ☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
  - ☐ 13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (BPC 4064.5[a][3])
  - ☐ 13.17.1.5. The pharmacist is exercising their professional judgment. (BPC 4064.5[a][4])
  - ☐ 13.17.1.6. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])
- ☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])
- ☐ 13.17.3. When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills. (BPC 4064.5[f][1])
- ☐ 13.17.4. When a pharmacist furnishes a self-administered hormonal contraceptive pursuant to BPC 4052.3 under protocols developed by the Board of Pharmacy, the pharmacist may furnish, at the patient’s request, up to a 12-month supply at one time. (BPC 4064.5[f][2])

Yes No N/A

☐☐☐ 13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a], [b], 4076.7, CCR 1744)

☐☐☐ 13.19. The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a], CCR 1744[b])

☐☐☐ 13.20. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” (BPC 4076.7)

☐☐☐ 13.21. When requested by a patient or patient representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appears on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

☐☐☐ 13.22. When a pharmacist furnishes ~~naloxone~~ federal FDA-approved opioid antagonists pursuant to the board of pharmacy’s approved protocol, the pharmacist complies with all the requirements listed in BPC 4052.01 and CCR 1746.3.

☐☐☐ 13.23. When the pharmacy furnishes naloxone or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished. (BPC 4119.8)

☐☐☐ 13.24. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency exclusively for use by employees of the law enforcement agency, who have completed training provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists, and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

☐☐☐ 13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that the information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy’s normal operating hours. A pharmacist provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine. A pharmacist informs each patient or patient’s guardian of immunization record sharing preferences detailed in HSC 120440(e). At the request of a patient, the pharmacist shall notify each patient’s primary care provider or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. The pharmacist shall also notify each pregnant patient’s prenatal care provider, if known, of any vaccine administered to the patient within 14 days. (CCR 1746.4[d],[e],-[f])

☐☐☐ 13.26. The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197a, and is furnished exclusively for use by, or in connection with, an authorized entity and an authorized health care provider provides a prescription specifying the quantity of the epinephrine auto-injectors to be furnished to the authorized entity. A new prescription is

obtained for any additional epinephrine auto-injector required for use. The pharmacy complies with the requirements for labeling and records pursuant to BPC 4119.4.

☐☐☐ 13.27. When a pharmacist initiates and furnishes HIV preexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.02. (BPC 4052.02, CCR 1747)

☐☐☐ 13.28. When a pharmacist initiates and furnishes HIV postexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.03. (BPC 4052.03, CCR 1747).

☐☐☐ 13.29. When a pharmacist receives a prescription, which include the words “expedited partner therapy” or the letters “EPT” pursuant to HSC 120582, the pharmacists labels the drug without the name of the individual for whom the drug is intended (BPC 4076 [a], [f]).

☐☐☐ 13.30. When a pharmacist provides EPT the pharmacist provides written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions. (BPC 4076[a], [h]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (BPC 4063)

☐☐☐ 14.2. Refills are documented. (CCR 1717)

☐☐☐ 14.3. Prescriptions for dangerous drugs or devices are only filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient’s ongoing care and have a significant adverse effect on the patient’s well-being. (BPC 4064[a])

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (HSC 11200)

☐☐☐ 14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (HSC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Auto-Refill Program

Yes No N/A

☐☐☐ 15.1. The pharmacy offers a program to automatically refill prescriptions (CCR 1717.5). The pharmacy is aware ~~that effective July 1, 2022,~~ the following actions are required:

- ☐ 15.1.1. The pharmacy has policies and procedures describing the program. (CCR 1717.5[a][1])
- ☐ 15.1.2. Before a patient enrolls, the pharmacy provides a written or electronic notice summarizing the program to the patient or patient's agent. (CCR 1717.5[a][2])
- ☐ 15.1.3. The pharmacy obtains an annual renewal of each prescription from the patient or patient's agent for each prescription refilled through the program. (CCR 1717.5[a][3])
- ☐ 15.1.4. The pharmacy maintains a copy of the written or electronic consent to enroll on file for one year from date of dispensing. (CCR 1717.5[a][4])
- ☐ 15.1.5. The pharmacy completes a drug regimen review for each prescription refilled through the program at the time of refill. (CCR 1717.5[a][5])
- ☐ 15.1.6. Each time a prescription is refilled through the program, the pharmacy provides the patient or patient's agent with a written or electronic notice that a prescription was refilled through the program. (CCR 1717.5[a][6])
- ☐ 15.1.7. The pharmacy documents and maintains records of patient withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and provides confirmation to the patient or patient's agent. (CCR 1717.5[a][7])
- ☐ 15.1.8. The pharmacy provides a full refund to the patient, patient's agent or payer for any prescription refilled through the program if the pharmacy was notified that the patient did not want the refill, regardless of the reason, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication. (CCR 1717.5[a][8])
- ☐ 15.1.9. The pharmacy makes available any written or electronic notification required by this section in alternate languages as required by state or federal law. (CCR 1717.5[a][9])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 16.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711)

☐☐☐ 16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 16.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], [c][3])

☐☐☐ 16.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ 16.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 16.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ☐ 16.6.1. Date, location, and participants in the quality assurance review;
- ☐ 16.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 16.6.3. Findings and determinations; and
- ☐ 16.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 16.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 16.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with BPC 4073 (generic substitution). (CCR 1716)

☐☐☐ 16.9. The community pharmacy shall report, no later than 14 days following the date of discovery of the error, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board (BPC 4113.1)

☐☐☐ 16.10 An outpatient hospital pharmacy is not required to report a medication error that meets the requirements of an adverse event, and that has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. (BPC 4113.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 17.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ 17.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (HSC 11153)

☐☐☐ 17.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

☐☐☐ 17.4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Prescription Transfer

Yes No N/A

☐☐☐ 18.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e])

☐☐☐ 18.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

☐☐☐ 18.3. For electronic data transmission prescriptions, at the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester (BPC 688 (g)), unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. ~~Unfulfilled controlled substance prescriptions received as electronic data transmission prescriptions are transferred or forwarded in compliance with Federal Law.~~ (21 CFR 1300, 1304, 1306, and 1311)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

Yes No N/A

☐☐☐ 18.4. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR 1306.25, CCR 1717[e])

☐☐☐ 18.5. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], 21 CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

19. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ 19.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ 19.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ 19.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ 19.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ 19.5. If the pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ 19.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. Record Keeping Requirements

Yes No N/A

☐☐☐ 20.1. All completed pharmacy self-assessments are on file in the pharmacy and maintained for three years. (CCR 1715[d])

☐☐☐ 20.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records. These records include (BPC 4052.04, 4081, 4105, 4169, 4333):

- ☐ 20.2.1. Prescription records (BPC 4081[a])
- ☐ 20.2.2. Purchase Invoices for all prescription drugs (BPC 4081[a])
- ☐ 20.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 20.2.4. Biennial controlled substances inventory (21 CFR 1304.11[c], CCR 1718)

☐ 20.2.5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

☐ 20.2.6. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05~~7~~)

☐ 20.2.7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 20.2.8. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081[a])

☐ 20.2.9. Record documenting transfers or sales to other pharmacies, licensees, prescribers, and reverse distributors (BPC 4081, 4105, CCR 1718)

☐ 20.2.10. Records of receipt and shipment (BPC 4081)

☐ 20.2.11. Record documenting kind and amounts of COVID-19 oral therapeutics furnished as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy (BPC 4052.04)

☐ 20.2.12. Records demonstrating compliance with medication error reporting requirements (BPC 4113.1[a])

Yes No N/A

☐☐☐ 20.3. A pharmacist may sell hypodermic needles and syringes to a person without a prescription is limited to: (BPC 4145.5)

☐ 20.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need; (BPC 4145.5[a])

☐ 20.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established. (BPC 4145.5[c])

☐ 20.3.3. For industrial use, as determined by the board. (BPC 4144.5)

☐ 20.3.4. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (BPC 4145.5[b])

☐☐☐ 20.4. When hypodermic needles and syringes are furnished by a pharmacy without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C, and safe disposal of sharps waste; and provide one or more of the following disposal options: (BPC 4145.5[e], [f])

☐ 20.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 20.4.2. Furnish or make available mail-back sharps containers.

☐ 20.4.3. Furnish or make available sharps containers.

☐☐☐ 20.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are

maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, BPC 4105[e])

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

Yes No N/A

☐☐☐ 20.6. The pharmacy furnishes an epinephrine auto-injector to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code if all of the following are met:

- ☐ 20.6.1. The epinephrine auto-injectors are furnished exclusively for use at a school district site, county office of education, or charter school (BPC 4119.2 [a][1]).
- ☐ 20.6.2. A physician and surgeon provide a written order that specifies the quantity of epinephrine auto-injectors to be furnished (BPC 4119.2[a][2]).

☐☐☐ 20.7. The pharmacy furnishes an epinephrine auto-injector to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197(a), provided that: (BPC 4119.3, 4119.4)

- ☐ 20.7.1. An authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed; (BPC 4119.3[a][1], 4119.4[a][2])
- ☐ 20.7.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only”, the dosage, use and expiration date; and~~.~~ (BPC 4119.3[a], 4119.4[b])
- ☐ 20.7.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (BPC 4119.3[a][2][B], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ 21.1. Is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11[c])

☐☐☐ 21.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 22. (21 CFR 1304.04[h][1])

☐☐☐ 21.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)

☐☐☐ 21.4. Indicates on the inventory record whether the inventory was taken at the “open of business” or at the “close of business.” (21 CFR 1304.11[a])

Yes No N/A

☐☐☐ 21.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])

☐☐☐ 21.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][4])

☐☐☐ 21.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

☐☐☐ 21.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all Schedule II controlled substances. When Schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])

☐☐☐ 21.9. When a pharmacy distributes Schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form 222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

☐☐☐ 21.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, a copy of the DEA Form 222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 21.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[a][1][iv]], Drug Supply Chain Security Act, BPC 4160)

☐☐☐ 21.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Department of Justice within 144 hours of the failure to provide prescription. (HSC 11167[c], [d])

☐☐☐ 21.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 21.14. ~~Any c~~ Controlled substances drug loss is reported within one business day of discovery to the DEA and within 30 days of discovery to the Board of Pharmacy of any loss of controlled substances in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed (21 CFR 1301.74[c], CCR 1715.6):

☐ 21.14.1. Tablets, capsules, or other oral medication, 99 dosage units

☐ 21.14.2. Single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

☐ 21.14.3. Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers.

Yes No N/A

☐☐☐ 21.15. Do pharmacy staff hand initial prescription records or prescription labels, or (CCR 1712, 1717[b][1])

☐☐☐ 21.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ 21.17. All Schedule II through ~~I~~V controlled substance dispensing data is successfully transmitted to CURES within one working day from the date the controlled substance is released to be patient. (HSC 11165[d])

☐☐☐ 21.18. Furnishing of dangerous drugs and controlled substances for physician office use is done under sales and purchase records that correctly give the date, names and addresses of supplier and buyer, the drug or device and its quantity. The prescription may not be used for obtaining dangerous drugs or controlled substances for supplying a practitioner for the purpose of dispensing to patients. (21 CFR 1306.04[b], HSC 11250, BPC 4059)

☐☐☐ 21.19. The pharmacy has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon discovering a suspicious order or series of orders, notify the DEA and the Special Agent in charge of DEA in their area. (21 USC 832[a]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 22.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 22.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

Yes No N/A

☐☐☐ 22.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This report requires: (CCR 1715.65 [c])

- ☐ 22.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 22.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 22.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 22.3.4. 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; and (CCR 1715.65[c][4])
- ☐ 22.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- ☐ 22.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])
- ☐ 22.3.7. An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the **reportable** loss. (CCR 1715.65)
- ☐ 22.3.8. Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])
- ☐ 22.3.9. The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The individual who performs the inventory shall sign and date the inventory or report. If not personally completed by the pharmacist-in-charge or professional director, the report must also be signed by the pharmacist-in-charge or professional director. (CCR 1715.65[e], [e][1])

☐☐☐ 22.4. The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

~~☐☐☐ 22.5. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])~~

Yes No N/A

☐☐☐ 22.65. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Oral/Electronic Transmission and Partial Fill of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 23.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], HSC 11164)

☐☐☐ 23.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], HSC 11167.5)

- ☐ 23.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- ☐ 23.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- ☐ 23.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- ☐ 23.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], HSC 11167.5)

☐☐☐ 23.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. The pharmacist shall notify the prescriber if the remaining portion of the prescription is not filled within 72 hours. (21 CFR 1306.13[a], CCR 1745[d])

☐☐☐ 23.4. The pharmacist maintains records (in a readily retrievable form or on the original prescription) of each partial filling (filled within 60 days from the date of prescription

issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as “terminally ill.” (21 CFR 1306.13[b], CCR 1745)

Yes No N/A

☐☐☐ 23.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance when a partial fill is requested by the patient or practitioner. The pharmacist shall report to CURES only the actual amounts of drug dispensed. The total dispensed shall not exceed the prescribed quantity. (21 USC 829[f], BPC 4052.10)

☐☐☐ 23.6. Controlled substances written with the “11159.2 exemption” for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (HSC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 23.7. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], HSC 11167)

☐☐☐ 23.8. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4[h])

☐☐☐ 23.9. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy’s computer memory. (CCR 1717.4[e])

☐☐☐ 23.10. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

☐☐☐ 23.11. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 23.12. A computer-generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05[d])

☐☐☐ 23.13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

☐☐☐ 23.14. Controlled substance prescriptions with the 11159.3 exemption during a declared local, state, or federal emergency, noticed by the board, may be dispensed if the following are met: (HSC 11159.3)

- ☐ The prescription contains the information specified in HSC 11164(a), indicates that the patient is affected by a declared emergency with the words “11159.3

exemption" or a similar statement, and is written and dispensed within the first two weeks of notice issued by the board.

- ☐ When the pharmacist fills the prescription, the pharmacist exercises appropriate professional judgment, including reviewing the patient's activity report from the CURES PDMP before dispensing the medication.
- ☐ If the prescription is a Schedule II controlled substance, the pharmacist dispenses no greater than the amount needed for a seven-day supply.
- ☐ The patient first demonstrates, to the satisfaction of the pharmacist, their inability to access medications, which may include, but not limited to, verification of residency within an evacuation area.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Automated Drug Delivery Systems

Yes	No	N/A	
☐	☐	☐	24.1. Does the pharmacy use an automated drug delivery system, automated patient dispensing system and/or automated unit dose system? (CCR 1713)

If yes, complete the biennial self-assessment for automated drug delivery systems.

Note: An ADDS license is not required for technology installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and devices. (BPC 4427.2[j]) or exempt AUDS operated by a licensed hospital pharmacy. (BPC 4427.2(i) As a reminder, a self-assessment form is required for an exempt AUDS.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. Repackaging by the Pharmacy

Yes	No	N/A	
☐	☐	☐	25.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], BPC 4342, HSC 110105, 111430)
☐	☐	☐	25.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)
☐	☐	☐	25.3. Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and includes the name and address of both pharmacies and complies with the other requirements of BPC 4052.7.

Yes No N/A

☐☐☐ 25.4. The pharmacy only repackages and furnishes a reasonable quantity of dangerous drugs and devices for prescriber office use. (BPC 4119.5 [b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. Refill Pharmacy

Yes No N/A

☐☐☐ 26.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ 26.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 26.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to the three questions above is “no” or “not applicable” go to section 27.

☐☐☐ 26.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 26.5. Refill prescription label meets requirements of BPC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 26.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

☐☐☐ 26.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 26.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 26.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 27.1. The pharmacy is a provider of blood clotting products for home use in compliance with HC 125286.20 and 125286.25. (HSC 125286.20, 125286.25)

- ☐ ~~27.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])~~
- ☐ ~~27.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])~~
- ☐ ~~27.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])~~
- ☐ ~~27.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])~~

~~☐☐☐ 27.2. The pharmacy meets the following requirements:~~

- ☐ ~~27.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])~~
- ☐ ~~27.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])~~
- ☐ ~~27.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])~~
- ☐ ~~27.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])~~
- ☐ ~~27.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])~~
- ☐ ~~27.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])~~
- ☐ ~~27.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])~~
- ☐ ~~27.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])~~
- ☐ ~~27.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])~~
- ☐ ~~27.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such~~

~~notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])~~

~~☐ 27.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])~~

~~☐ 27.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[*l*])~~

28. Policies and Procedures

Yes No N/A

☐☐☐ 28.1. There are written policies and procedures in place for:

☐ 28.1.1. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects their ability to practice the profession or occupation authorized by their license, including the reporting to the board within 14 days of receipt or development; (BPC 4104[a],[c])

☐ 28.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (BPC 4104[b], [c])

☐ 28.1.3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to HSC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (BPC 4074[a], CCR 1707.2[b][2])

☐ 28.1.4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, the pharmacist's responsibilities for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 28.1.5. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 28.1.6. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (BPC 4059.5[f][1])

☐ 28.1.7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 28.1.8. A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection; (BPC 733[b][3])

☐ 28.1.9. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; (BPC 733[b][1])

☐ 28.1.10. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language; and (CCR 1707.5[d])

☐ 28.1.11. Inventory reconciliation reporting requirements. (CCR 1715.65[b])

Yes No N/A

☐☐☐ 28.2. Does your pharmacy employ the use of a common electronic file? (CCR 1717.1)

☐ 28.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1[e])

☐☐☐ 28.3. Does your pharmacy furnish emergency contraceptives pursuant to BPC 4052.3[b][1]? (BPC 4052, CCR 1746)

If yes, does the pharmacy:

☐ 28.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746[b])

☐ 28.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746[b][4])

☐ 28.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746[b][8])

☐ 28.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (BPC 4052.3[b][2], CCR 1746[b][10])

☐ 28.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (BPC 773[b], CCR 1746[b][5])

☐ 28.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (BPC 733[b])

☐ 28.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified their employer in writing? (BPC 733[b][3], 4052.3)

Yes No N/A

☐☐☐ 28.4. Furnishes ~~naloxone hydrochloride~~ federal FDA-approved opioid antagonists in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.01[a], CCR 1746.3)

☐ 28.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 28.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

Yes No N/A

☐☐☐ 28.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.9, CCR 1746.2)

☐☐☐ 28.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.3, CCR 1746.1)

☐☐☐ 28.7. Does your pharmacy furnish travel medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section BPC 4052(a)(10)(A)(3)? If yes, does the pharmacy do the following: (CCR 1746.5[a], [c])

☐ 28.7.1. Keep documentation on site and available for inspection by the board, pharmacist(s) completion of an immunization training program that meets the requirements on BPC 4052.8(b)(1), completion of a travel medicine training program, consisting of at least 10 hours of training and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012) completion of the CDC Yellow Fever Vaccine Course; and current basic life support certification. (CCR 1746.5[c])

☐ 28.7.2. Pharmacists complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunization and vaccines, from an approved provider once every two years. (CCR 1746.5[d])

☐ 28.7.3. Prior to furnishing travel medications, the pharmacist performs a good faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history includes all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. (CCR 1746.5[e])

☐ 28.7.4. The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enters the appropriate information in the patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for their primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice. (CCR 1746.5[f])

☐ 28.7.5. A patient medication record is maintained and securely stored in a physical or electronic manner for each travel medication furnished, such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy's or facility's normal operating hours and the pharmacist provides the patient with written documentation that reflects the clinical assessment and travel medication plan. (CCR 1746.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

29. Compounding

Yes No N/A

☐☐☐ 29.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the “Compounding Self-Assessment” required by CCR 1735.2[k].

30. Nuclear Pharmacy

Yes No N/A

☐☐☐ 30.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 30.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 30.3. The pharmacy possesses a current Sterile Compounding Permit (BPC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, required by CCR 1735.2[k].

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

31. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

☐☐☐ 31.1. Pharmacy provides telepharmacy services and has obtained a remote dispensing site pharmacy license from the board. (BPC 4130[e], 4044.6, 4044.3[a])

If the answer is "yes", name the remote dispensing site pharmacy and license number:

Name: _____ License No.: _____

List the names of all qualified remote dispensing site pharmacy technician:

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

If the answer to the question above is “no” or “not applicable” go to section 32.

Yes No N/A

☐☐☐ 31.2. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131[b])

☐☐☐ 31.3. Both the supervising and remote dispensing site pharmacies operate in accordance with BPC 4130, 4131, 4132, 4133, 4134, 4135, 4044, 4044.3, 4044.6, 4044.7, 4059.5.

☐☐☐ 31.4. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130[h])

~~The supervising pharmacy uses a telepharmacy system for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at the remote dispensing site pharmacy. (BPC 4130[a], BPC 4044.7)~~

~~☐☐☐ 31.3. The remote dispensing site pharmacy is located in a medically underserved area unless otherwise approved by the board. (BPC 4130[c])~~

~~☐☐☐ 31.4. The remote dispensing site pharmacy does not employ any unlicensed personnel. (BPC 4130[d])~~

~~☐☐☐ 31.5. The supervising pharmacy has only obtained one remote dispensing site pharmacy license. (BPC 4130[e])~~

~~☐☐☐ 31.6. The remote dispensing site pharmacy is not operated by the state and is not located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. (BPC 4130[f])~~

~~☐☐☐ 31.7. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130[h])~~

~~☐☐☐ 31.8. The supervising pharmacy provides telepharmacy services for only one remote dispensing site pharmacy. (BPC 4131[a])~~

~~☐☐☐ 31.9. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131[b])~~

~~☐☐☐ 31.10. The supervising pharmacy and the remote dispensing site pharmacy are under common ownership. (BPC 4131[c])~~

~~☐☐☐ 31.11. The remote dispensing site pharmacy is staffed by a pharmacist, or at least one registered pharmacy technician meeting the qualifications of BPC section 4132 (BPC 4130[d]).~~

~~☐☐☐ 31.12. Pharmacy technicians working at a remote dispensing site pharmacy remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. (BPC 4131[d])~~

~~☐☐☐ 31.13. The supervising pharmacists utilizes a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy. (BPC 4131[d])~~

PIC Initials

☐☐☐ 31.14. The designated pharmacist-in-charge of the supervising pharmacy is also the pharmacist-in-charge at the remote dispensing site pharmacy. (BPC 4131[e])

☐☐☐ 31.15. The pharmacist -in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy are responsible to ensure that both the supervising pharmacy and the remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare. (BPC 4130[f])

☐☐☐ 31.16. In addition to the requirements of BPC 4202, a pharmacy technician working at the remote dispensing site pharmacy has met the requirements required by BPC 4132. (BPC 4132[a])

- ☐ Possess a pharmacy technician license that is in good standing.
- ☐ Possess and maintain a certification issued by the board-approved pharmacy technician certification program.
- ☐ Possess one of the following: a minimum of an associated degree in pharmacy technology, a minimum of a bachelor's degree in any subject, or a certification of completion from a course of training specified by regulations adopted by the board pursuant to BPC 4202.
- ☐ Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

☐☐☐ 31.17. Registered pharmacy technicians may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at the remote dispensing site pharmacy under the supervision of a pharmacist at the supervising pharmacy using a telepharmacy system. (BPC 4132[b])

☐☐☐ 31.18. Pharmacy technicians at the remote dispensing site pharmacy do not do any of the following:

- ☐ 31.18.1. Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law. (BPC 4132[c][1])
- ☐ 31.18.2. Consult with a patient or their agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart. (BPC 4132[c][2])
- ☐ 31.18.3. Identify, evaluate, or interpret a prescription. (BPC 4132[c][3])
- ☐ 31.18.4. Interpret the clinical data in a patient medication record system or patient chart. (BPC 4132[c][4])
- ☐ 31.18.5. Consult with any prescriber, nurse, or other health care professional or authorized agent thereof. (BPC 4132[c][5])
- ☐ 31.18.6. Supervise the packaging of drugs and check the packaging procedures and product upon completion. (BPC 4132[c][6])
- ☐ 31.18.7. Perform any function that requires the professional judgment of a licensed pharmacist. (BPC 4132[c][7])
- ☐ 31.18.8. Compound drug preparations. (BPC 4132[c][8])

☐☐☐ 31.19. A pharmacist at the supervising pharmacy supervises no more than two pharmacy technicians at each remote dispensing site pharmacy. The pharmacist may also supervise pharmacy technicians at the supervising pharmacy. (BPC 4132[d])

☐☐☐ 31.20. The supervising pharmacy's telepharmacy system maintains a video and audio communication system that provides for effective communication between the

supervising pharmacy and the remote dispensing site pharmacy's personnel and patients. (BPC 4133[a])

☐☐☐ 31.21. The telepharmacy system facilitates adequate pharmacist supervision and allows the appropriate exchange of visual verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs. (BPC 4133[b])

☐☐☐ 31.22. Patient counseling is provided using audio-visual communication prior to all prescriptions being dispensed from the remote dispensing site pharmacy. (BPC 4133[c])

☐☐☐ 31.23. The telepharmacy system is able to do all of the following:

- ☐ 31.23.1. Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription. (BPC 4133[d][1])
- ☐ 31.23.2. Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription. (BPC 4133[d][2])
- ☐ 31.23.3. Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed. (BPC 4133[d][3])
- ☐ 31.23.4. Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing. (BPC 4133[d][4])
- ☐ 31.23.5. Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery. (BPC 4133[d][5])

☐☐☐ 31.24. The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191). (BPC 4133[e])

☐☐☐ 31.25. All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription. (BPC 4133[f])

☐☐☐ 31.26. A pharmacist from the supervising pharmacy completes a monthly in-person, self-inspection of each remote dispensing site pharmacy using the form designated by the board and retains all inspection reports. (BPC 4134[a])

☐☐☐ 31.27. A perpetual inventory is kept for all controlled substances stored at the remote dispensing site pharmacy. (BPC 4134[b])

☐☐☐ 31.28. All controlled substances stored at the remote dispensing site pharmacy are stored in a secure cabinet or safe that is locked. (BPC 4134[c])

☐☐☐ 31.29. A pharmacist from the supervising pharmacy performs inventory and inventory reconciliation functions at the remote dispensing site pharmacy to detect and prevent the loss of any controlled substances. (BPC 4134[d])

☐☐☐ 31.30. The pharmacist-in-charge of the remote dispensing site pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of any controlled substances. (BPC 4134[e])

☐☐☐ 31.31. A pharmacist from the supervising pharmacy compiles an inventory reconciliation report of all Schedule II controlled substances at the remote dispensing site pharmacy at least once every three months. (BPC 4134[f]) This compilation shall include the following:

- ☐ 31.31.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. (BPC 4134[f][1])
- ☐ 31.31.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report. (BPC 4134[f][2])
- ☐ 31.31.3. A comparison of the two above-mentioned items to determine if there are any variances. (BPC 4134[f][3])
- ☐ 31.31.4. 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. (BPC 4134[f][4])

☐☐☐ 31.32. The remote dispensing site pharmacy reports in writing, any identified losses of controlled substances and possible causes of losses to the board within 31 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report is made within 14 days of discovery. If the remote dispensing site pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4134[g])

☐☐☐ 31.33. Possible causes of overages are identified in writing and incorporated into the inventory reconciliation report. (BPC 4134[h])

☐☐☐ 31.34. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy, and is readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (BPC 4134 [i])

☐☐☐ 31.35. While closed, the remote dispensing site pharmacy utilizes an alarm or other comparable monitoring system. (BPC 4135[a])

☐☐☐ 31.36. The remote dispensing site pharmacy is not open and its employees are not allowed access at times when the supervising pharmacy is closed. (BPC 4135[b])

☐☐☐ 31.37. The remote dispensing site pharmacy's security system tracks entries into the remote dispensing site pharmacy and the pharmacist-in-charge periodically review the record of entries. (BPC 4135[b])

☐☐☐ 31.38. Pharmacy services are not provided at the remote dispensing site pharmacy if the telepharmacy system is unavailable. (BPC 4135[b])

☐☐☐ 31.39. The remote dispensing site pharmacy retains a recording of facility surveillance excluding patient communications, for a minimum of 120 days. (BPC 4135[c])

☐☐☐ 31.40. Dangerous drugs and devices and controlled substances ordered by the remote dispensing site pharmacy are signed for and received by a pharmacist or a registered pharmacy technician, who meets the qualifications of Section 4132. (BPC 4059.5[g])

☐☐☐ 31.41. A controlled substance signed for by a pharmacy technician under BPC section 4059.5 is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[g])

☐☐☐ 31.42. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to BPC section 4059.5 is captured on video, and the video is accessible to the

~~supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days. (BPC 4059.5[g])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

32. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 32.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that applies to the type of program(s):

☐ Mail back envelopes or package service. (CCR 1776.2)

☐ Collection receptacles in the pharmacy. (CCR 1776.3)

☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

If the answer to the question above is "no" or "not applicable" go to section 33.

☐☐☐ 32.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[f])

☐☐☐ 32.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) are not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

☐☐☐ 32.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 32.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed of as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 32.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 32.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

☐☐☐ 32.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

Yes No N/A

☐☐☐ 32.9. The preaddressed envelope and package contain a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 32.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number: _____ Expiration Date: _____

☐☐☐ 32.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g][1])

Pharmacies with Collection Receptacles in the Pharmacy (CCR 1776.1, 1776.3)

Yes No N/A

☐☐☐ 32.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 32.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i][1])

Date the board was notified: _____

☐☐☐ 32.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 32.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 32.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

☐☐☐ 32.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

Yes No N/A

☐☐☐ 32.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[a])

☐☐☐ 32.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 32.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter. (CCR 1776.3[b])

☐☐☐ 32.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

☐☐☐ 32.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 32.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D1709 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

- ☐ 32.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle. (CCR 1776.3[f][1], [2])
- ☐ 32.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 32.23.3. The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 32.23.4. The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 32.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[g])

☐☐☐ 32.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling, and transport. (CCR 1776.3[h])

☐☐☐ 32.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their

rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

Yes No N/A

☐☐☐ 32.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 32.28. The pharmacy maintains records for collected unwanted drugs from consumers for three years, including the records for each liner identified in 1776(a). (CCR 1776.3[k], 1776.6[a])

☐☐☐ 32.29. The pharmacy seals the inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premises. (CCR 1776.3[l])

☐☐☐ 32.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) are not to be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 32.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 32.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the pharmacy requires the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 32.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs. (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

☐☐☐ 32.34. Was the board notified in writing within 30 days of establishing a collection receptacle? (CCR 1776.4[b][2])

☐☐☐ 32.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

Yes No N/A

☐☐☐ 32.36. When the pharmacy license was renewed, did the pharmacy provide ~~the list~~ a current list of collection receptacles? (CCR 1776.4[b][6])

☐☐☐ 32.37. The skilled nursing facility places patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

☐☐☐ 32.38. The collection receptacle is located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner? (CCR 1776.4[e][f][g])

☐☐☐ 32.39. The liner certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 32.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 32.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 32.42. The rigid container is disposable, reusable, or recyclable. The rigid container is leak resistant, has sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 32.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) cannot be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 32.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 32.45. The installation, removal, transfer, and storage of inner liners is performed only by: (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

Yes No N/A

☐☐☐ 32.46. Sealed inner liners placed in a container are stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

☐☐☐ 32.47. Liners housed in a rigid container are delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

☐☐☐ 32.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 32.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 32.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])
- ☐ 32.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- ☐ 32.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- ☐ 32.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])
- ☐ 32.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

33. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 33.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202.5, 150204, BPC 4169.5)

- ☐ 33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (HSC 150202.5)
- ☐ 33.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)

☐☐☐ 33.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (BPC 4169.5)

☐☐☐ 33.3. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☐ 33.4. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])

- ☐ 33.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 33.4.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 33.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])
- ☐ 33.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 33.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

34. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 34.1. The pharmacy conducts a county-approved drug repository and distribution program. (HSC 150201[b][1], 150204)

- ☐ 34.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (HSC 150201[b][1])
  - ☐ 34.1.1.1. Is county owned (HSC 150201[b][1]) or

☐ 34.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (HSC 150201[b][1], 150200, 150204[b][1])

☐ 34.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (HSC 150201[b][2])

Yes No N/A

☐☐☐ 34.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (HSC 150204[a][5])

Issued By: _____ Date: _____

☐☐☐ 34.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (HSC 150204[a][3])

☐☐☐ 34.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (HSC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 34.5. The pharmacy complies with the county's established written procedures. (HSC 150204[b])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Drugs and Maintenance of Drug Stock

Yes No N/A

☐☐☐ 34.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (HSC 150204[j])

☐☐☐ 34.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (HSC 150204[k])

☐☐☐ 34.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])

☐☐☐ 34.9. Donated medications received are unused, unexpired and meet the following requirements: (HSC 150202, 150202.5, 150204[c])

☐ 34.9.1. Are received from authorized sources. (HSC 150202, 150203)

☐ 34.9.2. No controlled substances are received. (HSC 150204[c][1])

☐ 34.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (HSC 150204[c][2])

☐ 34.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of

facility, and were never in the possession of a patient or member of the public. (HSC 150204[c][3])

☐ 34.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 150204[d])

☐ 34.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (HSC 150204[i])

☐ 34.9.7. For donated medication that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

Yes No N/A

☐☐☐ 34.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (HSC 150204[d][1], 150204[h])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Transferring Donated Drugs From One Participating Entity to Another

Yes No N/A

☐☐☐ 34.11. The pharmacy transfers donated medication to another participating county-owned pharmacy within an adjacent county. (HSC 150204[g][4])

☐☐☐ 34.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (HSC 150204[g][4][A])

Adjacent counties to which donated medication are transferred:

_____

_____

☐☐☐ 34.13. Donated medication is not transferred by any participating entity more than once. (HSC 150204[g][4][B])

☐☐☐ 34.14. When transferring donated medication, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (HSC 150204[g][4][C])

☐☐☐ 34.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (HSC 150204[g][4][C])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Dispensing to Eligible Patients

Yes No N/A

☐☐☐ 34.16. Donated medications that are dispensed to an eligible patient who presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (HSC 150204[i])

☐☐☐ 34.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (HSC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ _____ Date
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____ Date
Pharmacy Owner or Hospital Administrator

PIC Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

- Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 3 – Clinical Laboratory Technology
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
- CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
- CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006
- Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
- HSC, Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services
- HSC, Division 116 – Surplus Medication Collection and Distribution
- United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
- USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legend: Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and dashed underline for added language.

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code (BPC) to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge**. **The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, pursuant to 16 CCR 1715) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 pursuant to 16 CCR 1735.2(k).)

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: ☐ Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust
☐ Non-Licensed Owner ☐ Other (please specify) _____ - ____
License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License #_____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy staff (pharmacists, interns, technicians):
APH= Advanced Practice Pharmacist, DEA = Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

_____
PIC
Initials

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, 4117, CCR 1714)

☐☐☐ 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects their ability to practice the profession or occupation authorized by their license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (BPC 4104[a])

☐☐☐ 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (BPC 4104[b])

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting their ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects their ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects their ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (BPC 4104[c])

☐☐☐ 1.5. The pharmacy maintains a supply of medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714[b])

☐☐☐ 1.7. The pharmacy premises**,** fixtures**,** and equipment are maintained in a clean and orderly condition. (CCR 1714[c])

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714[c])

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714[g])

PIC Initials

Yes No N/A

☐☐☐ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (BPC 4032, 4058)

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (BPC 680, 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?

(If yes, complete the Compounding Self-Assessment required by CCR 1735.2[k])

☐☐☐ 1.13. The pharmacy is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.15. All medicinal cannabis is stored in a locked container in the patient's room, other designated areas, or with the patient's primary caregiver and is retrieved, administered, handled, removed and disposed in accordance with HSC 1649.1, 1649.2, 1649.3, 1649.4.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern pharmacist, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (BPC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern pharmacist shall report any irregularities to the pharmacist. (BPC 4119.7[c])

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director or chief executive officer of the health care facility within 24 hours. (BPC 4115[~~i~~j][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PIC Initials

3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (BPC 4059.5[a])

☐☐☐ 3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (BPC 4059.5[c])

☐☐☐ 3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (BPC 4059.5[f])

- ☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy; (BPC 4059.5[f][1])
- ☐ 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered; (BPC 4059.5[f][2])
- ☐ 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered; (BPC 4059.5[f][3])
- ☐ 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility; and (BPC 4059.5[f][4])
- ☐ 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (BPC 4059.5[f][5])

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])

PIC Initials

Yes No N/A

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

☐☐☐ 3.7. ~~The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023 unit-level traceability~~. The pharmacy has lot-level traceability and by November 27, 2023 will have unit-level traceability in accordance with the Drug Quality and Security Act (DQSA). (21 USC 360eee-1[d][2] and 582[g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (21 USC sections 331, 351, 352, BPC 4169[a][2]-[4], 4342, HSC 111255, 111335, CCR 1714 ~~([~~b]~~)~~, 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. Records of drugs taken from the drug stock or drug supplies must be maintained and the pharmacist must be notified. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales) or to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need. (BPC 4380, CCR 1710[a])

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (BPC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (BPC 4119.7[b]

☐☐☐ 4.6. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169, CCR 1718.1)

☐ 4.6.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.

☐ 4.6.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.

☐ 4.6.3. Are not expired.

Yes No N/A

☐☐☐ 4.7. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 4.8. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 4.9. An automated unit dose system (AUDS) operated by a licensed hospital pharmacy as defined by BPC 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility shall be exempted from the requirement of obtaining an ADDS license if the hospital pharmacy owns or leases the AUDS and owns the dangerous drugs or devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS (i.e. Security, Record keeping, Self-Assessment, Quality Assurance, etc.) and maintain a list of the location of each AUDS it operates. (BPC 4119.11[b][3], 4427.2, 4427.65)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

~~(If yes, complete Section 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)~~

5.1.1. The pharmacy that donates medications to or operates a voluntary county approved drug repository and distribution program meets all the requirements as specified in law. (HSC 150200, 150201, 150202, 150202.5, 150203, 150204, 150204.5, 150204.6, 150205, BPC 4169.5)

~~5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202, 150202.5, 150204)~~

~~☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (HSC 150202.5)~~

~~☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)~~

~~☐☐☐ 5.2. No controlled substances shall be donated. (HSC 150204[c][1])~~

~~☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])~~

~~☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])~~

~~☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])~~

~~☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])~~

~~☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])~~

~~☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])~~

~~☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101, 4330)

☐☐☐ 6.5. The PIC is not concurrently serving as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailer. (CCR 1709.1[d])

☐☐☐ 6.6. The PIC or pharmacist, if PIC is not available, may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation. (BPC 4113[c][2])

_____
PIC
Initials

☐☐☐ 6.7. The PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the board is timely notified. (BPC 4113[d][1]

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. A pharmacist: (BPC 4019, 4051, 4052, 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- ☐ 7.1.1. Receives a chart order for an inpatient; (BPC 4019, 4051-[b], 4052, 4052.2, CCR 1717, CCR 1793.1[a])
- ☐ 7.1.2. Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- ☐ 7.1.3. Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], 4052.2[a][4], CCR 1793.1[d])
- ☐ 7.1.4. Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- ☐ 7.1.5. Calculates drug doses; (BPC 4052-[a][3], 4052.2-[a][3], 4052.2-[a][4])
- ☐ 7.1.6. Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- ☐ 7.1.7. Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])
- ☐ 7.1.8. Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, 4052.2, CCR 1793.1[g])

☐☐☐ 7.2. Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (BPC 4027, 4051, 4052, 4052.2)

- ☐ 7.2.1. Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- ☐ 7.2.2. Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2],-[3]; 4052.2[a][2],-[3])
- ☐ 7.2.3. Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])

- ☐ 7.2.4. Performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in BPC section 4052.2[d]. (BPC 4052.4)
- ☐ 7.2.5. A pharmacist may perform any aspect of any FDA-approved or authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 USC Sec 263a) and the pharmacist completes the testing in a pharmacy laboratory that is licensed in California as a laboratory pursuant to BPC section 1265 unless otherwise authorized in law. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedure maintained in subsection be of BPC section 4119.10 and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition or disease being tested as applicable. (BPC 4052.4)

Yes No N/A

☐☐☐ 7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (BPC 4052[b])

☐☐☐ 7.4. All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. Upon approval, the DOJ shall release to the pharmacist or their delegate the CURES information for an individual under the pharmacist's care. (HSC 11165.1)

☐☐☐ 7.5. All pharmacists have joined the board's email notification list. (BPC 4013)

☐☐☐ 7.6 The hospital pharmacist (or pharmacy technician or an intern pharmacist if both requirements of BPC 4118.5(b) are met) shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patients if the hospital has more than 100 beds, the accurate medication profile is acquired during hospital pharmacy's hours of operation. (BPC 4118.5)

☐☐☐ 7.7. The pharmacist may initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority. (BPC 4052[a][13], [14])

☐☐☐ 7.8. Only a prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in BPC 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. (BPC 4071.1)

☐☐☐ 7.9. A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification of medication chart order (BPC 4071.1[d][1], 4071.1[2][a]).

PIC Initials

☐☐☐ 7.10. Until January 1, 2025, a pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2, the virus that cause COVID-19when the following are met (BPC 4052.04 [a]):

- ☐ 7.10.1. Prior to furnishing COVID-19 oral therapeutics pursuant to 4052.04(a), a pharmacist utilizes relevant and appropriate evidence-based clinical guidelines published by the federal Food and Drug Administration in providing these patient care services; (BPC 4052.04[b])
- ☐ 7.10.2. A pharmacist notifies the patient's primary care provider, enter the appropriate information in a patient record system shared with the primary care provider or if the patient does not have a primary care provider, provides the patient a written record of the drugs furnished and advises the patient to consult a physician of the patient's choice; (BPC 4052.04[c])
- ☐ 7.10.3 A pharmacist documents the kind and amounts of COVID-19 oral therapeutics furnished pursuant to 4052 (a), as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. These records shall be maintained for three years and shall be available for inspection by all properly authorized personnel of the board (BPC 4052.04[d])

☐☐☐ 7.11. A pharmacist shall submit proof satisfactory to the Board that they have successfully completed 30 hours of approved courses of continuing pharmacy education, including at least one hour of participation in a "cultural competency course", (as defined in BPC 4231) during the two years preceding the application for renewal. (BPC 4231, 4233, 4234, CCR 1732,1732.05, 1732.1, 1732.2, 1732.3, 1732.4, 1732.5, 1735.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 8.1 The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])
- ☐ 8.1.3 Initiate, adjust or discontinue drug therapy and shall promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[a][5], [b])
- ☐ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[b])

☐ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])

☐ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (BPC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (BPC 4119.6)

☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty-free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], [c], [d]; CCR 1726)

☐☐☐ 9.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)

☐☐☐ 10.2. The ratio is not less than one pharmacist on duty for two technicians when filling prescriptions for an inpatient of a licensed health facility. (BPC 4115[g~~f~~], CCR 1793.7[f])

_____
PIC Initials

☐☐☐ 10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing packaging, manipulative, repetitive, or other nondiscretionary tasks. If a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, a second pharmacy technician shall be assisting a pharmacist with performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[g~~f~~][1], CCR 1793.7[f])

☐☐☐ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies them as a pharmacy technician or pharmacy technician trainee. (BPC 680, BPC 4115.5[e], CCR 1793.7[d])

☐☐☐ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty-free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (BPC 4115[h~~g~~], CCR 1714.1[c])

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

Yes No N/A

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (BPC 4119, 4115[j~~i~~])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (BPC 4115[j~~i~~])

PIC Initials

☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (BPC 4115[~~i~~i])

☐☐☐ 10.10. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

☐☐☐ 10.11. A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions (BPC 4115[b][1]):

☐ 10.11.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist (BPC 4115[b][1][A]):

☐ 10.11.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board (BPC 4115[b][1][B], BPC 4202[a][4]):

☐ 10.11.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C] and

☐ 10.11.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

☐☐☐ 10.12. A pharmacy technician submits proof satisfactory to the Board of successfully completing at least one hour of participation in a "cultural competency course" (as defined in BPC 4231) during the two years preceding the application for renewal. (BPC 4202)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (BPC 4007, CCR 1793.3)

☐☐☐ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (BPC 688, 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by BPC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (BPC 688, 4019, 4040, 22 CCR 70263[g])

_____
PIC
Initials

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. An order for controlled substance for use by a patient in a county or licensed hospital shall be in the patient's records and the record of such orders shall be maintained as a hospital record for a minimum of seven years. (HSC 11159, BPC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (BPC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication are properly labeled and include the information as required by BPC 4076, or the information is otherwise readily available at the time of drug administration. (BPC 4076[b])

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 Cal. Code of Regs 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (BPC 4126.5[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (BPC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (BPC 688, CCR 1717.4)

☐☐☐ 16.5. Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

Yes No N/A

☐☐☐ 16.6. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711)

☐☐☐ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

☐☐☐ 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

☐ 17.6.1. Date, location, and participants in the quality assurance review;

☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;

☐ 17.6.3. Findings and determinations;

☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with BPC 4073 (generic substitution). (CCR 1716)

☐☐☐ 17.9. The PIC is reporting the quality assurance review reports for medication errors for all ADDS to the Board at the time of annual renewal of the hospital pharmacy license. (CCR 1711[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. All completed pharmacy self-assessments are on file in the pharmacy and are maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. These records include:

☐ 18.2.1. Prescription records (BPC 4081[a])

☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (BPC 4081)

☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)

☐ 18.2.4. U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13, 21 CFR 1305.22)

☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)

☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies, ~~and~~ prescribers, and reverse distributors. (BPC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (HSC 150200, 150202[a][1], 150204[k], BPC 4105[c]).

☐ 18.2.10. Record documenting kind and amounts of COVID-19 oral therapeutics furnished as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. (BPC 4052.04)

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Drug Supply Chain Security Act (DSCSA), BPC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, DSCSA, BPC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

Yes No N/A

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

☐☐☐ 18.11. Any controlled substances drug loss is reported ~~upon~~ within one business day of discovery to the DEA and within 30 days of discovery to the Board of Pharmacy for the following: ~~within 30 days.~~ (21 CFR 1301.74[c], CCR 1715.6)

☐ 18.11.1. Tablets, capsules, or other oral medication, 99 dosage units

☐ 18.11.2. Single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosages units.

☐ 18.11.3. Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers.

☐☐☐ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are

maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

☐☐☐ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 19.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. Inpatient hospital pharmacy reports shall include controlled substances stored within the pharmacy, within each satellite location, and within each drug storage area in the hospital. (CCR 1715.65[a], CCR 1715.65[g])

Yes No N/A

☐☐☐ 19.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65[b])

☐☐☐ 19.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65[c])

- ☐ 19.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 19.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 19.3.4. 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; and (CCR 1715.65[c][4])
- ☐ 19.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- ☐ 19.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and

promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])

☐ 19.3.7. An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the **reportable** loss. (CCR 1715.65)

☐ 19.3.8. Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

☐ 19.3.9. The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file. (CCR 1715.65[e][1])

☐ 19.3.10. Inpatient hospital pharmacy, the inventory reconciliation for all federal Schedule II-controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls must be performed on a quarterly basis. The report or reports shall include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. (CCR 1715.65[g])

☐☐☐ 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4104, CCR 1715.65[d], CCR 1715.6)

Yes No N/A

~~☐☐☐ 19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])~~

☐☐☐ 19.6~~5~~ A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

~~☐☐☐ 19.7 A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])~~

~~☐☐☐ 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that: (CCR 1715.65[h])~~

~~☐ 19.8.1 All controlled substances added to an automated drug delivery system are accounted for; (CCR 1715.65[h][1])~~

PIC Initials

- ~~19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel; (CCR 1715.65[h][2])~~
- ~~19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and (CCR 1715.65[h][3])~~
- ~~19.8.4 Confirmed losses of controlled substances are reported to the board. (CCR 1715.65[h][4])~~

☐☐☐ 19.8. The inpatient hospital pharmacy uses an ADDS, inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. (CCR 1715.65[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. After-Hours Supply of Medication

Yes No N/A

☐☐☐ 20.1 The pharmacy has a system assuring the prescribed medications are available in the hospital 24 hours a day. (22 CCR 70263[e])

☐☐☐ 20.2. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ 21.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ 21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1], BPC 4115, 4119.6))

☐☐☐ 21.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy's written inspection policies and procedures. (22 CCR 70263[f][3], BPC 4115[ji][3], 4119.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ 22.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (BPC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Emergency Room Dispensing

Yes No N/A

☐☐☐ 23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (BPC 4068[a])

- ☐ 23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or ~~I~~V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d])
- ☐ 23.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ☐ 23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;
- ☐ 23.17. If an ADDS is located in the emergency room and is used for dispensing to patients upon discharge, the ADDS is licensed with the Board. (BPC 4427.2[i]).

Yes No N/A

☐☐☐ 23.2. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (BPC 4068[b])

PIC Initials

☐☐☐ 23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (BPC 4076, CCR 1717)

☐☐☐ 23.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 23.6. Prescriptions are dispensed in new, senior-adult ease-of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ 23.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

☐☐☐ 23.8. The pharmacy provides patients with required Black Box Warning Information. (21 CFR 201.57[c])

☐☐☐ 23.9. Medication guides are provided on required medications. (21 CFR Part 208)

☐☐☐ 23.10. Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” (BPC 4076.7).

☐☐☐ 23.11. A pharmacist may dispense a drug prescribed pursuant to HSC Section 120582 and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words “expedited partner therapy” or the letters “EPT” and shall provide written notification that describes the right of an individual who received EPT to consult with a pharmacist about the medication dispensed and possible drug interactions. (BPC 4076[f], [h])

☐☐☐ 23.12. If emergency department patient dispensing is done via AUDS, the AUDS is licensed by the Board. (BPC 4427.2[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ 24.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (BPC 4074, CCR 1707.2)

☐☐☐ 24.2. Prescriptions are transmitted to another pharmacy as required by law. (BPC 4072, CCR 1717[c], [f], 1717.4)

☐☐☐ 24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 24.4. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074 [a], [b], CCR 1744[a][1]-[7])

☐☐☐ 24.5 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container (BPC 4074[a], CCR 1744[b][1]-[6]).

☐☐☐ 24.6. The trade name or generic name and manufacturer of the prescription drug is accurately identified in the prescription record. (CCR 1717)

☐☐☐ 24.7. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (BPC 4073)

☐☐☐ 24.8. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product or can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means and is immediately retrievable in the pharmacy. (CCR 1712, 1793.7)

☐☐☐ 24.9. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 24.10. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473, 16 CFR 1700.15, CCR 1717)

☐☐☐ 24.11. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

Yes No N/A

☐☐☐ 24.12. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

☐☐☐ 24.13. Medication guides are provided on required medications. (21 CFR Part 208)

☐☐☐ 24.14. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7).

☐☐☐ 24.15. ~~Effective January 1, 2022, t~~ The pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688)

☐☐☐ 24.16. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or V controlled substance, transmits the dispensing data to the

Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ 25.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy within this state receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 25.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy:

If the answer to this and the previous question is "no" or "not applicable" go to Section 26.

☐☐☐ 25.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])

☐☐☐ 25.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ 25.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ 25.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (BPC 4076[b], [c], [d], CCR 1710[b][3])

☐☐☐ 25.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

26. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 26.1 Prior to engaging in centralized hospital packaging, the pharmacy in addition to the hospital pharmacy license, has obtained a Centralized Hospital Packaging specialty license from the Board (BPC 4128.2a)

License Number: _____

☐☐☐ 26.2. The pharmacy prepares medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located within a 75-mile radius: (BPC 4128)

Hospitals to which central packaged unit dose medications are provided:

☐ 26.2.1. _____ Distance (miles): _____

_____
PIC
Initials

- ☐ 26.2.2. _____ Distance (miles): _____
- ☐ 26.2.3. _____ Distance (miles): _____
- ☐ 26.2.4. _____ Distance (miles): _____
- ☐ 26.2.5. Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.6. Prepares sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.7. Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

☐☐☐ 26.3. The pharmacy prepares and stores limited quantities of unit dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (BPC 4128.3)

☐☐☐ 26.4. Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded to be machine readable at the inpatient's bedside using barcode medication administrative software. (BPC 4128.4)

- ☐ 26.4.1. The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. (BPC 4128[a])
- ☐ 26.4.2. The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient. [BPC 4128(b)]

☐☐☐ 26.54. Any label for each unit dose medication produced by a centralized hospital packaging pharmacy displays a human-readable label that contains the following: (BPC 4128.5[a])

- ☐ 26.5.1. The date the medication was prepared.
- ☐ 26.5.2. The beyond-use date
- ☐ 26.5.3. The established name of the drug.
- ☐ 26.5.4. The quantity of each active ingredient.
- ☐ 26.5.5. The lot number or control number assigned by the centralized hospital packaging pharmacy.
- ☐ 26.5.6. Special storage or handling requirements.
- ☐ 26.5.7. The name of the centralized hospital packaging pharmacy.

Yes No N/A

☐☐☐ 26.6. The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

- ☐ 26.6.1. The components used in the drug product.
- ☐ 26.6.2. The expiration date of each of the drug's components.

☐ 26.6.3. The National Drug Code Directory number.

☐☐☐ 26.7. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (BPC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

27. Policies and Procedures

Yes No N/A

☐☐☐ 27.1. There are written policies and procedures in place for:

- ☐ 27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2[b][2])
- ☐ 27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects their ability to practice the profession or occupation authorized by their license. (BPC 4104[a])
- ☐ 27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (BPC 4104[b])
- ☐ 27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (BPC 4104[b])
- ☐ 27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in BPC 4104[c][1]-[6].
- ☐ 27.1.6. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- ☐ 27.1.7. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- ☐ 27.1.8. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)
- ☐ 27.1.9. Inventory reconciliation reporting requirements. (CCR 1715.65)

_____
PIC
Initials

- ☐ 27.1.10. Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility. (BPC 4115[~~j~~i][3])
- ☐ 27.1.11. Intern pharmacist, under the direct supervision and control of a pharmacist, may inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])
- ☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[a])
- ☐ 27.1.13. Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. (BPC 4119.7[b], 22 CCR 70263 [c][1], [q][6])
- ☐ 27.1.14. Establishing the supply contents, procedure for use, restocking and sealing of emergency drug supply. (CCR 70263[f][1])
- ☐ 27.1.15. If applicable, dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside. (22 CCR 70263[*l*])
- ☐ 27.1.16. The use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator's written orders. (22 CCR 70263[o]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

28. Compounding

Yes No N/A

☐☐☐ Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" as required by CCR 1735.2. (CCR 1735.2)

29. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 29.1. The hospital pharmacy operates automated drug delivery systems that are automated unit dose systems (AUDS) for doses administered at the facility and approved services listed on the hospital's license and the ADDS is/are exempt from licensure with the board. The AUDS must comply with all other requirements for an ADDS in Article 25. (BPC 4427.2[i])

☐☐☐ 29.2. The hospital pharmacy operates automated drug delivery systems that are automated patient delivery dispensing systems (APDS) for doses dispensed to patients at the

facility and approved services listed on the hospital's license and the ADDS is/are licensed with the board. (BPC 4427.2[a])

☐☐☐ 29.3. If the pharmacy operates an automated drug delivery system, the pharmacist-in-charge has completed the self-assessment for automated drug delivery systems pursuant to CCR 1715. The pharmacy shall comply with all recording keeping and quality assurance requirements and maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. (BPC 4427.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

30. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 30.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state, and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that apply to the type of program(s):

- ☐ Mail back envelopes or package service. (CCR 1776.2)
- ☐ Collection receptacles in the pharmacy. (CCR 1776.3)
- ☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[f])

☐☐☐ 30.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) are not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

Yes No N/A

☐☐☐ 30.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 30.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 30.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 30.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

☐☐☐ 30.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 30.9. The preaddressed envelope and package contains a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 30.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number: _____

Expiration Date: _____

☐☐☐ 30.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____
PIC
Initials

Pharmacies with Collection Receptacles in the Pharmacy/Hospital (CCR 1776.1, 1776.3)

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 30.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i])

Date the board was notified: _____

☐☐☐ 30.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 30.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

☐☐☐ 30.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 30.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[a], [d])

☐☐☐ 30.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter or is located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle is locked so that drugs are not deposited into the collection receptacle. (CCR 1776.3[b], [c])

☐☐☐ 30.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

PIC Initials

Yes No N/A

☐☐☐ 30.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR1776.3[f])

- ☐ 30.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle. (CCR 1776.3[f])
- ☐ 30.23.2 The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[g])
- ☐ 30.23.3 The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 30.23.4 The liner is removable as specified pursuant to CCR 1776.3. (CCR 1776.3[f][2])

☐☐☐ 30.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[d], [e], [g])

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 1776.3[h])

☐☐☐ 30.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 30.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 30.28. The pharmacy maintain records for collected unwanted drugs from consumers for three years, including the records for each liner. (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a reversed distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premise. (CCR 1776.3[l])

_____
PIC Initials

Yes No N/A

☐☐☐ 30.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) shall not to be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Onsite Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 30.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or persons lawfully entitled to dispose of a resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 30.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 30.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs? (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

☐☐☐ 30.34. The board was notified in writing within 30 days of establishing a collection receptacle. (CCR 1776.4[b][2])

☐☐☐ 30.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

- ☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 30.36. When the pharmacy license was renewed, the pharmacy provide the list a current list of collection receptacles. (CCR 1776.4[b][6])

☐☐☐ 30.37. The skilled nursing facility places a patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

_____
PIC
Initials

Yes No N/A

☐☐☐ 30.38. The collection receptacle is located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, has a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner. (CCR 1776.4[e][f][g])

☐☐☐ 30.39. The liner is certified by the manufacturer to meet the American Society for Testing Materials(ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes, is waterproof, tamper evident, tear resistant, and opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 30.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 30.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 30.42. The rigid container is either disposable, reusable, or recyclable. The rigid container is leak resistant, has sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 30.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) can not be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 30.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 30.45. The installation, removal, transfer, and storage of inner liners is performed only by (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 30.46. Sealed inner liners placed in a container are stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

PIC Initials

Yes No N/A

☐☐☐ 30.47. Liners housed in a rigid container are delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

☐☐☐ 30.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 30.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 30.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])
- ☐ 30.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- ☐ 30.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- ☐ 30.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])
- ☐ 30.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PIC Initials

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected by _____ (date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ _____ Date

(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____ Date

(Hospital Administrator)

PIC Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

- Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
- CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs
- CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
- CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice
- Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- HSC, Division 116 – Surplus Medication Collection and Distribution
- United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legend: Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and dashed underline for added language.

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~21~~19.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Title 16 of the California Code of Regulations section 1784 requires each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The designated representative-in-charge or responsible manager must also complete a self-assessment within 30 days whenever: (1) a new license has been issued; (2) there is a change in the designated representative-in-charge or responsible manager; or (3) there is a change in the licensed location of the wholesaler or third-party logistics provider. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Each self-assessment must be kept on file by the wholesaler and third-party logistics provider for three years after it is completed.

Licensed Premises Name: _____

Address: _____

Phone: _____

Licensed Premises Email address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

License #_____ Expiration Date_____

Other License #_____ Expiration Date_____

(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours

DRIC / RM _____

DR License # / RPH License #_____ Expiration Date_____

Website Address (optional): _____

Other Licensed Staff (DR, pharmacist (RPH)):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC.

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a],-[c],-[f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (BPC 4082)

☐ ☐ ☐ 1.3. Has there been a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued? Written notification to the board is required of within 30 days of the transfer. (CCR 1709[b]) **Please attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.4. Is there any beneficial interest of the WLS/3PL held in a trust? (CCR 1709[d]) **If yes, please have a copy of the trust readily available for inspection.**

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents and insects
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair
☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see the standards set forth in the latest edition of the USP) (CCR 1780[b])

Yes No N/A

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity? (CCR 1780[e])

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs or dangerous devices are stored limited to authorized personnel? (BPC 4116, 4167, CCR 1780[c])

List personnel with keys to the area(s) where dangerous drugs or dangerous devices are stored (list by name or job title):

_____

_____

_____

☐ ☐ ☐ 2.5. Does this business operate only when a DR or pharmacist is on the premises? (CCR 1781)

2.6. The licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, or others, by receiving, inventorying, and managing the disposition of outdated or nonsaleable dangerous drugs or dangerous devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices. (BPC 4163~~([c])~~[])

Date of approval from the board: _____

Yes No N/A

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

☐ ☐ ☐ 3.6. The DRIC/RM has provided an electronic mail address to the board and shall maintain a current electronic mail address, if any, with the board and must notify the board within 30 days of any change of electronic mail address, giving both the old and new electronic mail address. (CCR 1704[b])

☐ ☐ ☐ 3.7. The DRIC/RM has completed a wholesaler or third-party logistics provider self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new license has been issued; there is a change in the DRIC/RM; or there is a change in the licensed location of the wholesaler or third-party logistics provider. Each self-assessment will be maintained by the wholesaler or third-party logistics provider for three years. (CCR 1784)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (BPC 4163[b], 4169)

☐ ☐ ☐ 4.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (BPC 4081, 4332)

☐ ☐ ☐ 4.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 5.1. When drugs are received by your business, are they delivered to the licensed premises, and received by and signed for only by a DR or a pharmacist? (BPC 4059.5[a])

☐ ☐ ☐ 5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling of controlled substances – these additional requirements are in Section 11 of this document.

6. Drug Stock

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☐ ☐ ☐ 6.2. Are all drugs you order maintained in a secure manner at your licensed premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (BPC 4167)

☐ ☐ ☐ 6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (BPC 4342[a])

☐ ☐ ☐ 6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e])

☐ ☐ ☐ 6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e])

☐ ☐ ☐ 6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling of controlled substances – these additional requirements are in Section 11 of this document.

7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 7.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

7.2. Describe how you verify a business or person is appropriately licensed. (BPC 4059.5[a],[b],[d],[g], ~~BPC~~ 4169)

_____

_____

7.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (BPC 4163[a]) Note: An authorized person can be a business or natural person.

7.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and your business only furnishes ~~O~~only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

☐ ☐ ☐ 7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 7.6.1. transacted with a business licensed with this board as a WLS/3PL or pharmacy?

☐ ☐ ☐ 7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

7.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (BPC 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ 7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

☐ ☐ ☐ 7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

☐ ☐ ☐ 7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, BPC 651, CCR 1766)

☐ ☐ ☐ 7.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (BPC 650)

_____

_____

☐ ☐ ☐ 7.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (BPC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling of controlled substances – these additional requirements are in Section 11 of this document.

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)

Yes No N/A

☐ ☐ ☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

☐ ☐ ☐ 8.2. No controlled substances shall be donated. (HSC 150204[c][1])

☐ ☐ ☐ 8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150204[c])

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])

☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

☐ 8.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 9.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company —UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (BPC 4166[a])

9.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling of controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (BPC 4059.5[a])

☐ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the ~~manufacturer's~~ manufacturers or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (BPC 4059.5[d])

☐ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (BPC 4059.5[c])

☐ ☐ ☐ 10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a],[c],[e])

☐ ☐ ☐ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (HSC 11153.5[a],[b],[c])

☐ ☐ ☐ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received, and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

Yes No N/A

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74[g])

☐ ☐ ☐ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

☐ ☐ ☐ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form~~,~~ of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board of ~~any loss of controlled substances~~ within 30 days of discovering the loss of the following:~~?~~

☐ Any loss of a controlled substance, in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:

☐ (A) For tablets, capsules, or other oral medication, 99 dosage units.

☐ (B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

☐ (C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers. (CCR 1715.6)

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs

☐ ☐ ☐ 12.1.2. Security of drugs

☐ ☐ ☐ 12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ 12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ 12.1.5. Distributing drugs

☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

Yes No N/A

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 12.1.9. drugs that have been partially used~~2~~.

☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality, or purity (CCR 1780[e],[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☐ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient's name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (BPC 4059[b])

☐ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081, 4105[c], 4332)

☐ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☐ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

☐ ☐ ☐ 15.6. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☐ ☐ ☐ 15.7. Are required records stored off-site only if a board issued written waiver has been granted?

☐ ☐ ☐ 15.8. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 15.9. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 15.10. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

☐ ☐ ☐ 15.11. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (BPC 4105[d][2])

☐ ☐ ☐ 15.12. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation: (BPC 4162[a][5])~~:~~

_____

_____

☐ ☐ ☐ 15.14. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

☐ ☐ ☐ 15.15. Has this licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☐ 15.16. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling of controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination. (BPC 4101[b], 4305.5[c].

☐ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager. (BPC 4305.5[a])

☐ ☐ ☐ 16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

☐ ☐ ☐ 16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

☐ ☐ ☐ 16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

☐ ☐ ☐ 16.8. The wholesaler maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ☐ 16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities
- ☐ 16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ 16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☐ ☐ ☐ 16.9. I understand that this license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (BPC 4201[g])

☐ ☐ ☐ 16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise

arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 16.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 16.12. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

☐ ☐ ☐ 16.13. The wholesaler/third party logistics provider shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. A temporary closure shall not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. (CCR 1708.1)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

17.1. List all licenses and permits required to conduct this business, including local business licenses, licenses held in other states, permits or licenses required by foreign countries or other entities (BPC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the premises license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov, at the California State Law Library, or at other libraries or Internet websites:

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulations (CCR), Title 16, Division 17 – California State Board of Pharmacy

Code of Federal Regulations (CFR), Title 21, Chapter 2 – Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law, Chapter 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

Attachment 9

Board of Pharmacy

Enforcement Workload Statistics FY 2023/24

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	822	817	0	0	1,639
Closed	768	603	0	0	1,371
					Quarter Ending
Pending	1,932	2,203	0	0	2,203
Average Days for Investigation	213	198	0	0	198

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	745	987	0	0	987
Drug Diversion / Fraud	241	238	0	0	238
Prescription Drug Abuse	221	240	0	0	240
Compounding	40	43	0	0	43
Outsourcing	16	22	0	0	22
Probation / PRP	42	36	0	0	36
Enforcement	53	41	0	0	41
Criminal Conviction	571	594	0	0	594

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	64	56	0	0	120
Closed					
Approved	28	29	0	0	57
Denied	7	17	0	0	24
Total Closed (includes withdrawn)	***38***	***47***	***0***	***0***	***85***
					Quarter Ending
Pending	102	113	0	0	113

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	229	185	0	0	414
Non-Jurisdictional	115	105	0	0	220
No Violation	51	54	0	0	105
No Further Action	33	28	0	0	61
Other - Non-Substantiated	59	27	0	0	86
Subject Educated	21	16	0	0	37

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	47	48	0	0	95
Citations Issued	270	160	0	0	430
Proof of Abatement Requested	36	25	0	0	61
Appeals Referred to AG's Office	42	10	0	0	52
Dismissed	3	12	0	0	15
Total Fines Collected	***$702,692***	***$370,263***	***$0***	***$0***	***$1,072,955***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	78	64	0	0	142
Pleadings Filed	75	53	0	0	128
Total Closed	46	57	0	0	103
Pending					Quarter Ending
Pre-Accusation	144	137	0	0	137
Post-Accusation	169	185	0	0	185
Total Pending	**313**	**322**	**0**	**0**	**322**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	4	0	0	6
Intern Pharmacist	0	2	0	0	2
Pharmacy Technician	8	15	0	0	23
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	3	0	0	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***24***	***0***	***0***	***35***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***0***	***0***	***0***	***1***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	8	8	0	0	16
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	3	0	0	7
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	4	0	0	6
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***14***	***15***	***0***	***0***	***29***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	2	1	0	0	3
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	3	0	0	4
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	1	0	0	1
Outsourcing	0	0	0	0	0
Total	***4***	***5***	***0***	***0***	***9***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	6	4	0	0	10
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	1	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***8***	***5***	***0***	***0***	***13***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	0	0	0
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	0	1	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	1	0	0	0	1
Total	***2***	***1***	***0***	***0***	***3***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***1***	***0***	***0***	***2***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$361,102***	***$211,270***	***$0***	***$0***	***$572,372***
Cost Recovery Collected	***$254,954***	***$203,035***	***$0***	***$0***	***$457,989***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	1	2	0	0	3
Automatic Suspension Orders	1	1	0	0	2
Penal Code 23 Restrictions	2	4	0	0	6
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	1	0	0	1
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	164	164	0	0	164
Intern Pharmacist	2	1	0	0	1
Pharmacy Technician	20	21	0	0	21
Designated Representative	1	1	0	0	1
Wholesaler / 3PL	2	2	0	0	2
Pharmacy	52	53	0	0	53
Sterile Compounding	9	10	0	0	10
Outsourcing	0	0	0	0	0
Total	***250***	***252***	***0***	***0***	***252***
Probation Compliance Measures					Total
Probation Office Conferences	18	16	0	0	34
Probation Interviews / Site Inspections	141	117	0	0	258
Probation Terminated / Completed	25	16	0	0	41
Referred to AG for Non-Compliance	0	0	0	0	0

As of 12/31/2023

Board of Pharmacy

Citation and Fine Statistics FY 2023/24

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	24	21	0	0	45
Pharmacist-in-Charge with Fine*	13	13	0	0	26
Pharmacist no Fine	78	28	0	0	106
Pharmacist-in-Charge no Fine*	48	25	0	0	73
Pharmacy with Fine	134	87	0	0	221
Pharmacy no Fine	22	14	0	0	36
Pharmacy Technician with Fine	4	0	0	0	4
Pharmacy Technician no Fine	7	2	0	0	9
Wholesalers	0	1	0	0	1
Designated Representative	1	1	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	0	0	1
Hospital Pharmacy	2	2	0	0	4
Miscellaneous**	17	5	0	0	22
Unlicensed Premises	2	0	0	0	2
Unlicensed Person	0	1	0	0	1

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	23%	1716 - Variation from prescription	22%	1716 - Variation from prescription	24%
1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	14%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in- charge	22%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	13%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	14%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	15%	1715.6 - Reporting drug loss	11%
1715.6 - Reporting drug loss	11%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	10%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	11%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	9%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in- charge shall constitute grounds for disciplinary action	7%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	8%
1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	7%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	6%	4059(a) - Furnishing dangerous drugs without a prescription	8%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	7%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	8%
1735.4(a)(2) - Labeling of Compounded Drug Preparation- Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least Name (brand or generic) and s	7%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%	1735.4(a)(2) - Labeling of Compounded Drug Preparation- Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least Name (brand or generic) and s	8%
4059(a) - Furnishing dangerous drugs without a prescription	5%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	4%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%
1735.2(g) - Compounding Limitations and Requirements- The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality and labeled strength of a compounded drug	5%	4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	4%	1735.2(i)(1)(A) - Compounding Limitations and Requirements	5%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through June 2024.

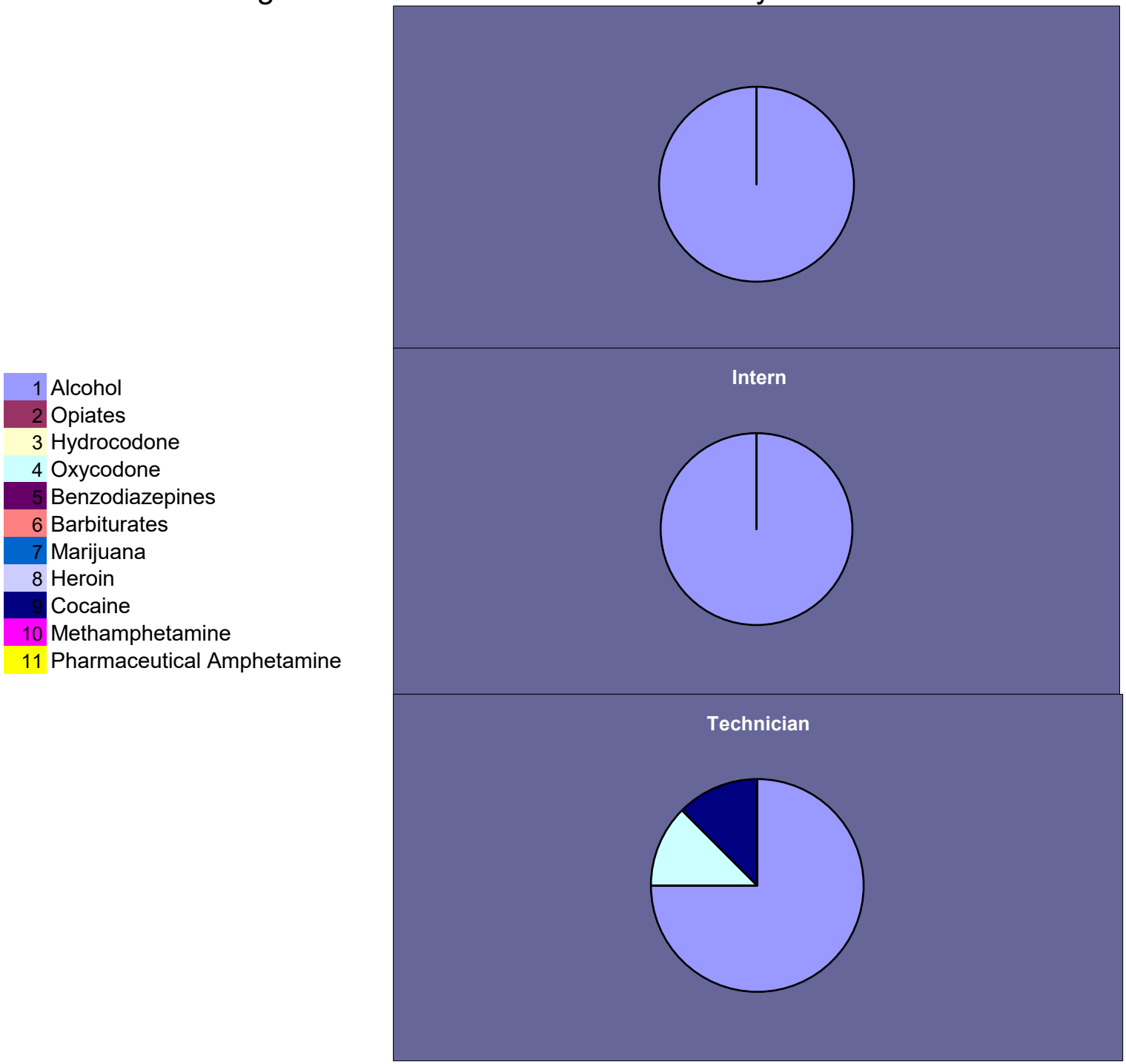
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	23/24
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	1	1			2
PRP Under Investigation	2				2
PRP In Lieu Of (investigation conducted)	2				2
Total Number of PRP Intakes	5	1			6
New Probationers					
Pharmacists		6			6
Intern Pharmacists	1				1
Pharmacy Technicians	4	4			8
Total New Probationers	5	10			15
PRP Participants and Recovery Agreements					
Total PRP Participants	28	25			N/A
Recovery Agreements Reviewed	23	18			41
Probationers and Inspections					
Total Probationers	40	44			N/A
Inspections Completed	20	21			41
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	404	414			818
Drug Tests Conducted (PRP and Probationers)	389	407			796
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	3	1			4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationer	7	3			10
Termination from PRP	2				2
Probationers Referred for Discipline	1				1
Closure					
Successful Completion (PRP and Probationers)	3				3
Termination (Probation)	1				1
Voluntary Surrender (Probation)	1	4			5
Surrender as a result of PTR (Probation)	1	1			2
Closed Public Risk (PRP)	2				2
Non-compliance (PRP and Probationers)	10	16			26
Other (PRP)	2	2			4
Patients Harmed					
Number of Patients Harmed (PRP and Probationers					Zero
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 23/24**
Alcohol	2	1			3
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2023 through June 2024.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	23/24
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
	-	-	-	-	
Alcohol	2				
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
	-	-	-	-	
Alcohol	4	2			
Opiates					
Hydrocodone					
Oxycodone		1			
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine		1			
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2023 to December 2023



Printed on 1/16/2024