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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee Report

Members:

Greg Lippe, Public Member, Chairperson
Ryan Brooks, Public Member
Kenneth Schell, PharmD
Debbie Veale, PharmD

LICENSING COMMITTEE REPORT AND ACTION

Report of the Meeting held on October 5, 2010.

a. **FOR DISCUSSION AND ACTION: Review and Action Regarding Review and Approval of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies.**

Attachment 1

Background

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are 1) already licensed pharmacies, and 2) compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

Currently the board has 243 such licensed facilities in California and 93 nonresident pharmacies with such permits.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health
- AND
- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board (JCAHO).

Currently there are two accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc. (ACHC), and 2. Community Health Accreditation Program (CHAP).

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited

by one of three accreditation agencies. Recently, the board modified its regulations for pharmacies that compound medication. Included in these regulations are modified requirements for pharmacies that compound sterile injectable medication. These regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, took effect July 6, 2010. (The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.)

Since 2003, when both agencies were approved by the board, board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Both agencies were last reviewed by the board in 2006.

- 1. Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
- 2. Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
- 3. Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
- 4. Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
- 5. Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
- 6. Board access to accreditor's report on individual pharmacies.**
- 7. Length of time the accrediting agency has been operating.**
- 8. Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

During the April 2010 Board Meeting, the board directed that the following occur:

1. Review and assess the three accreditation agencies
2. Report the findings to the Licensing Committee
3. Bring committee recommendations to the full board

The board also voted to extend the approval of the two already approved accreditation agencies, ACHC and CHAP, for one year until April 2011.

Committee Discussion/Action

During the committee meeting, the committee was provided with a summary of the board staff's finding in evaluating the accreditation process used by JCAHO as it compares to board criteria. (The committee was advised that the ACHC and CHAP were unable to attend the meeting.) During the meeting a representative from JCAHO responded to

committee member questions about their current accreditation process. Concern was expressed about the current practice of JCAHO to extend accreditation to newly licensed hospitals that are under common control with existing accredited facilities and the possible conflict with our statutory requirements.

Also during the meeting, the committee discussed whether a pharmacist should participate in the accreditation surveys. The committee offers the following recommendation for board consideration.

MOTION: LICENSING COMMITTEE: Request that JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.

b. FOR DISCUSSION and POSSIBLE ACTION: Proposal to Initiate Regulation Changes Regarding Application Requirements for Intern Pharmacists and Pharmacists to Require “Self-Query” Reports from the National Practitioner Data Bank - - Healthcare Integrity and Protection Data Bank (NPDB/HIPDB)

Attachment 2

Background

The board currently reports information regarding its licensees who have been disciplined or otherwise had an adverse action to the NPDB/HIPDB required by law. In addition to our reporting, all adverse actions taken by federal or state agencies, exclusions of health care practitioners in federal or state programs, criminal convictions, and civil judgments are also required to be reported to the NPDB/HIPDB. NPDB/HIPDB serves as the repository of data for all such actions taken against healthcare practitioners.

It is not unusual for a pharmacist applicant or intern to also be licensed in other jurisdictions. As part of the application process for both the intern and pharmacist exam application, applicants are required to self-disclose several items. The intern application includes several questions surrounding prior disciplinary action has ever been taken in this state or any other.

The pharmacist exam application includes several of the same types of questions as well as information about licensure in other states. This information is all self-certified by the applicant. In addition, the board requires license verification, where identified by the pharmacist applicant.

At the July Board Meeting, the board approved a proposal to require pharmacists and pharmacist interns to provide a “self query” report from the National Practitioner Data Bank-- Healthcare Integrity and Protection Data Bank (NPDB/HIPDB) as a condition of application for licensure in California.

Committee Discussion/Action

MOTION: LICENSING COMMITTEE: Authorize the Executive Officer to initiate the rulemaking processes to adopt the language that has been proposed. (A copy of the proposed language is provided in **Attachment 2.**)

c. FOR DISCUSSION and POSSIBLE ACTION: Proposal to Initiate Regulation Changes to Update the Pharmacy Technician Application and to Add an Application

Requirement for Pharmacy Technicians to Require “Self-Query” Reports from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB/HIPDB)

Attachment 3

Background

At the July Board Meeting, staff advised the board that about 50 percent of the technician applications submitted to the board have one or more deficiencies. This slows the processing of the application and delays licensure for qualified applicants. Staff believes that the proposed modifications will help reduce processing time for applicants and ensure that those technicians disciplined by other states are known to the board before California issues a pharmacy technician license. As a result, the board directed staff to make modifications to the pharmacy technician application that will reduce the number of deficiencies in submitted applications.

The board subsequently directed staff to add a requirement that a “self query” report from the National Practitioner Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB/HIPDB) be added as an application requirement for pharmacy technicians.

Committee Discussion/Action

The committee reviewed proposed modifications to the pharmacy technician application and was advised that because this applications is incorporated by reference into the regulation section, the board will need update the regulation via the rulemaking process to use the revised application. Further, the additional requirement for self-query from the NPDB- HIPDB will ensure that disciplinary action in other states will be provided to the board at the time a licensing decision is being made.

MOTION: LICENSING COMMITTEE: Authorize the executive officer to take all steps necessary to initiate the rulemaking to update the application form and NPDB/HIPDB self-query report as presented. (A copy of the proposed language and revised application form is provided in **Attachment 3**.)

d. FOR INFORMATION: Request from PETNET Solutions for a Waiver of Security Requirements for Pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present.

Attachment 4

Last year, the board was contacted by PETNET Solutions, a radiopharmacy operating in 44 states, for exemptions from several California Pharmacy Law provision regarding pharmacy security. Their initial request is provided on the following pages.

PETNET Solutions has requested the opportunity to appear before the board to request an exemption. Below is a summary of the request:

PETNET is petitioning the board to grant certain waivers to California Pharmacy Law to cover the following California pharmacies:

- PETNET Solutions, Inc, Palo Alto, license # PHY 48657
- PETNET Solutions, Inc., Sacramento, license # PHY 48660
- PETNET Solutions, Inc., Irvine, license # PHY 48659

- PETNET Solutions, Inc., Culver City, license # PHY 48658

PETNET requested the following waivers:

1. Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a)
 - **Waiver Request:** Allow personnel listed as Cyclotron Operator/Engineer on the Radioactive Material License access to the permitted space (pharmacy area) during non-operational hours without the presence of a pharmacist for the sole purpose of maintenance and repair of the cyclotron, automated synthesis equipment, and quality control testing equipment.
2. California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d) and (f)
 - **Waiver Request 1714(d):** Allow the CO (Cyclotron Operator/Engineer) access to the permitted pharmacy space by issuing cipher lock combination numbers to the CO. A conventional key will not be issued.
 - **Waiver Request 1714(f):** Allow an applicant for a licensed premise or for a renewal of that license to certify that it meets the requirements of Section 1714 and to attach a copy of the waiver to said application, should the board grant a waiver, or comply with other actions as determined by the board.

According to the board's attorneys, the board lacks the authority to waive California pharmacy law in the manner requested. It has the ability to waive regulations of the board under conditions of 1706. (**Attachment 4** contains a copy of the request submitted by PETNET as well as copies of the existing law for the provisions listed above.)

Committee Discussion/Action

The committee discussed this issue and sought clarification on the safeguards in place and was advised that some equipment could be locked up when the pharmacy was closed. The committee was advised that the board does not have the authority to waive a statutory requirement. Ms. Herold offered that a possible solution would be a legislative change. Ms. Herold suggested that a narrowly drafted statutory change to Business and Professions Code section 4116, may allow PETNET to obtain the authorization it seeks. Ms. Herold indicated that should section 4116 be amended, the board could then consider the waiver request to California Code of Regulations Section 1714.

The committee did not take action on this item.

e. **FOR DISCUSSION: Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**

Background

Pharmacists are required to earn 30 hours of approved continuing education credit every two years as a condition of renewal. Requirements for continuing education in both statute and regulation follow this page. Pharmacy technicians are not required to earn CE to maintain board licensure, although to be certified by the Pharmacy Technician Certification Board (a method to qualify for initial registration), they have a CE requirement.

At several prior meetings of the board or its committees, including the last meeting of the Licensing Committee, there was general discussion about developing requirements for

pharmacists to earn CE in specific subject matter areas. Establishing such a requirement would take either a legislative or regulation change.

Committee Discussion/Action

The committee discussed previous content requiring continuing education as well as the requirements in other states that specify course content. The committee identified some possible content areas ranging from patient consultation to ethics. It was suggested that the committee may want to first determine the goal of the specific CE requirement.

The committee did not take action on this item, but requested that it be brought back to the committee for further discussion.

f. **FOR INFORMATION: Department of Consumer Affairs' Request that Health Care Boards Evaluate the Federal Healthcare Reform Act's Impact on Present and Future Licensees and their Licensing Acts.**

The committee was advised that in March, the Federal Health Care Reform Act was enacted federally and advised the committee that since that time, the director has asked that the board examine how it will affect how health care is delivered in California, particularly to prepare for larger number of patients.

Under a separate agenda item the Board will hear a presentation from Manatt Health Solutions on Implementing Effects of Federal Healthcare Reform.

g. **FOR INFORMATION: Competency Committee Report**

Attachment 5

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

The board instituted a quality assurance review of the CPJE effective August 2, 2010. This process is done periodically to ensure the reliability of the examination. This review has since been completed and results are currently being released.

Attachment 5 contains examination statistics which contains the pass rate for the CPJE from April 1, 2010 to September 30, 2010.

Examination Development

Both Competency Committee workgroups met in August 2010 at the annual meeting to discuss examination development. Each Competency Committee workgroup will also meet once in the fall of 2010 for examination development. Each workgroup will ensure the new outline will be used to develop examinations administered after April 1, 2011.

Committee Discussion/Action

The committee took no action.

h. FOR INFORMATION: Licensing Statistics 2010/11

Attachment 6

Attachment 6 includes the licensing statistics for first quarter 2010/11.

i. FOR INFORMATION: Minutes of the Meeting Held on October 5, 2010

Attachment 7

A summary of the meeting held on October 5, 2010 is provided in **Attachment 7**.

j. FOR INFORMATION: First Quarterly Report on Licensing Committee Goals for 2010-11

Attachment 8

The first quarterly report on the Licensing Committee's goals is provided at the back of the tab section in **Attachment 8**.

Attachment 1

Table 1. Review of Accreditation Agencies required by Business and Professions Code Section 4127.1(d)

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (JCAHO)
1. Periodic Inspections	Accreditation is valid for 3 years, requiring a full site inspection.	Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.	Triennial inspection for accreditation with annual ISO periodic inspections.	Accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional 3 months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected. The vast majority of surveys are conducted by the three year anniversary date. However, if requested by the CA BOP, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure resurveys are performed no more than 36 months after the previous full survey.
2. Comparison of standards	Copy of pharmacy standards submitted.	Copy of pharmacy standards submitted.	Comparison table of standards to regulations was submitted.	Refer to crosswalk comparison submitted.
3. Surveyor's qualifications.	<ul style="list-style-type: none"> •Maintain a current pharmacist license in one of the 50 states or territories of the U.S. •Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred. •Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey. 	<ul style="list-style-type: none"> •CHAP site visitors are required to have at least 5 years middle senior management experience in the service line in which they perform site visits. •Only a pharmacist would be assigned to survey a pharmacy. •All new staff receives a 5-day classroom orientation and 4 to 6 site visits where they are assigned an experienced pharmacy site visitor preceptor. •Job description provided. 	<ul style="list-style-type: none"> •Will make every effort to ensure a pharmacist participates as a member of the survey team when a hospital seeks to demonstrate compliance to sterile compounding requirements. •Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training. •All surveyors are evaluated in terms of their interpersonal skills. 	<ul style="list-style-type: none"> •In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience. •Pharmacist must have a Doctor of Pharmacy degree or equivalent. •Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline.

<p>(qualifications – continue)</p>	<ul style="list-style-type: none"> •Must attend an annual full day training session. •Must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards. •Are evaluated annually for their ability to perform surveys in accordance with ACHC p/p. 		<ul style="list-style-type: none"> •Must complete 45 hours of continuing education in their discipline within every 3 year period. •Must participate in annual surveyor training 	<ul style="list-style-type: none"> •All surveyors must have five years of recent experience, including three year of direct clinical experience in the appropriate health care setting and two years of senior management experience. •All surveyors participate in a training and competency assessment process. •New surveyors begins with a one-week classroom educational program specifically tailored to their setting. •New surveyors complete a minimum of three surveys with a preceptor in the field, and must pass the Surveyor Certification Examination. New surveyors are terminated if they fail the exam after three attempts. •Surveyors must pass a re-certification exam every five years. •Continuing/ongoing surveyor education includes an annual on-site training conference each January. Surveyors participate in a quarterly educational conference call. Every other week, surveyors receive an email addressing topics of interest. •All surveyors receive official newsletters with updates on new standards •All surveyors receive an annual performance evaluation.
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<p>4. Acceptance by major California payors</p>	<p>ACHC is recognized by most major payors. In CA, Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.</p>	<ul style="list-style-type: none"> •Is accepted by major payors everywhere. Works effectively and ongoing with all payors to educate them about CHAP, and the robustness of the accreditation process. (List of specific payor sources not provided). •CMS (Medicaid and Medi-Care) 	<p>Medi-Caid and Medi-Care (CMS) approval 9/26/2008.</p>	<p>Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California.</p>
<p>5. Subjected to Unannounced inspections by BOP</p>	<p>ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board.</p>	<ul style="list-style-type: none"> •CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability. 	<ul style="list-style-type: none"> •Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved. 	<p>Pharmacies subjected to the compounding regulations are accredited under The Joint Commission’s Comprehensive Accreditation Manual for Home Care – Pharmacy standards.</p> <p>List of accredited pharmacies was provided.</p>
<p>6. Access to accreditor’s reports on individual pharmacies.</p>	<ul style="list-style-type: none"> •ACHC will make available to CA BOP any provider’s summary of findings as requested. •The Board can access current accredited provider by visiting ACHC website. 	<ul style="list-style-type: none"> •CHAP agreements allow CHAP to disclose accreditation reports to certain authority, which include the CA BOP. •CHAP standards also required accredited organizations to disclose this information with a copy of the written report available on site. A process for providing reports on demand can be established. 	<p>Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required.</p>	<p>Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. Should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.</p>

7. Length of time accrediting agency has been operating as an accrediting agency.	ACHC is an independent, private, not for profit corporation established in 1986.	<ul style="list-style-type: none"> •CHAP was founded in 1965 as the first organization in the U.S. to accredit community based health care organizations. •CHAP is authorized by CMS to provide accreditation for home health, hospice, durable medical equipment and pharmacy. 	<ul style="list-style-type: none"> •Established in 1864 in Oslo, Norway with 15 offices in the U.S. •In U.S. since 1898. •DNVHS offices in Houston Texas and Cincinnati, Ohio. •300 offices in over 100 countries. 	The Joint Commission has been in operations as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.
8. Ability to accredit out-of-state pharmacies.	ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.	As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.	•Refer to #7	The Joint Commission can and does accredit pharmacies throughout the United States.
9. Annual submission of list of accredited board of licensed facilities.	List received.	<ul style="list-style-type: none"> •CHAP has 6 currently accredited pharmacy sites in CA. •Current list submitted 6/4/2010. 	Currently, Hoag Medical Center is the only pharmacy accredited by DNV in CA. Hoag also maintains an LSC license until DNV is approved by the BOP.	List received. Also an internet search is available on The Joint Commission website to verify accreditation.

Table 3. Summary of Findings of Accredited Pharmacies Inspections (Refer to Criteria #5)

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (JCAHO)
Record keeping (CCR 1751.1, 1735.2, 1735.3)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Add to compounding sheet equipment used. • Unable to retrieve electronic data for temperature monitoring.	Pharmacy #1 • Reviewed.	Pharmacy #1 •Supplies invoices not on premise for 3 years. •Add to compounding sheet equipment used.
	Pharmacy #2 • Reviewed. • Document cleaning of TPN Compounder. • No c/s DEA inventory.	Pharmacy #2		Pharmacy #2 • Compounding records missing expiration date of final product. • Require record of manufacturer or supplier of each component. • Add to compounding sheet equipment used.
Labeling (CCR 1751.2, 1735.4)	Pharmacy #1 • New labeling implemented identifying products that are compounded.	Pharmacy #1 • Add statement the drug was compounded by pharmacy. • Label needs to contain generic name of drug.	Pharmacy #1 • Label on container missing name of prescriber. • Add statement the drug was compounded by pharmacy.	Pharmacy #1 •Add statement the drug was compounded by pharmacy.
	Pharmacy #2 • Add Chemo – Dispose properly label. • Add statement the drug was compounded by the pharmacy.	Pharmacy #2 • Add statement the drug was compounded by pharmacy		Pharmacy #2 • Add generic name to label . • Add statement the drug was compounded by pharmacy.
Policy and procedures (CCR 1751.3, 1735.5)	Pharmacy #1 • Need p/p for QA program regarding potency, strength, integrity and quality.	Pharmacy #1 •Revise p/p to weekly cleaning of surfaces: walls, ceilings, workbench surfaces. • Need p/p for QA program regarding integrity, potency, quality and strength.	Pharmacy #1 • Need to update p/p to reflect new changes in compound laws. • Revise p/p to weekly cleaning of surfaces: walls, ceiling, workbench surfaces.	Pharmacy #1 •Need p/p for QA program regarding integrity, potency, quality and strength. • Need p/p for use of equipment, including cleaning, maintenance, calibration, training.
	Pharmacy #2 • Add Chemo p/p. • Revise p/p to weekly cleaning of surfaces, walls, ceiling, workbench.	Pharmacy #2 • Update p/p to reflect training of staff on new p/p. • Revise p/p to weekly cleaning of surfaces: walls, ceiling, workbench surfaces.		Pharmacy #2 • P/P overdue for annual review. • Unable to locate recall p/p. • Change p/p to weekly cleaning of surfaces: walls,

				ceiling, workbench surfaces. • Need p/p for QA program regarding integrity, potency, quality and strength.
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Facility equipment (CCR 1751.4)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Refrigerator/Freezer requiring defrosting. • Expired frozen drugs need to be quarantined and properly disposed.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Temperature logs unavailable
	Pharmacy #2	Pharmacy #2 • Card board boxes in cleanroom. • 4 refrigerators with only 1 being monitored; no thermometers. All containing drugs.		Pharmacy #2

Attire (CCR 1751.5)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.
	Pharmacy #2 • Need to order chemo spill kit and chemo gown/gloves	Pharmacy #2 • Reviewed.		Pharmacy #2 • Reviewed

Training staff, patient, caregiver (CCR 1751.6)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Competency testing due.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.
	Pharmacy #2 • Reviewed.	Pharmacy #2 • Annual Competency testing overdue.		Pharmacy #2 • Add testing of terminology. • Annual retesting of competency overdue.

Quality assurance and process validation (CCR 1751.7)	Pharmacy #1 • Does end product testing for sterility, pyrogen testing only. • Conduct QA testing on products mailed, temperature of drug when sent to cold and hot places.	Pharmacy #1 • Only sterility testing and end product testing conducted.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.
	Pharmacy #2	Pharmacy #2 • Not documenting corrective actions when QA testing on personnel performance, equipment and facility fails.		Pharmacy #2 • Reviewed.

Reference materials (CCR 1751.8)	Pharmacy #1	Pharmacy #1 • Reviewed.		Pharmacy #1 •Reviewed.
	Pharmacy #2	Pharmacy #2 • Reviewed.		Pharmacy #2 • Reviewed.

California Board of Pharmacy – Joint Commission Request for Continued Recognition Under Business and Professions Code 4127.1

1. Periodic inspections: The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.

An accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional three months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected as well. In reality, the vast majority of surveys are conducted by the three year anniversary date. However, if requested by the California Board of Pharmacy, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure that resurveys are performed no more than 36 months after the previous full survey.

2. Documented accreditation standards: The standards granting accreditation and scoring guidelines for those standards must reflect both applicable California Law and sound professional practice as established by nationally recognized professional and standard setting organization.

See attached crosswalk comparing the requirements of the Board of Pharmacy - California Code of Regulations and the applicable Joint Commission standards and elements of performance.

3. Evaluation of surveyor's qualifications: The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.

Attached is a copy of the job description for a Joint Commission surveyor. In general, surveyors reviewing pharmacies subject to these regulations are licensed pharmacists or licensed registered nurses with infusion experience. Pharmacists must have a Doctor of Pharmacy degree (Pharm.D.) or equivalent. Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline. All surveyors must have five years of recent experience, including three years of direct clinical experience in the appropriate health care setting, and two years of senior management experience.

All Joint Commission surveyors participate in a training and competency assessment process. New surveyor training begins with a one-week classroom educational program specifically tailored to their setting. This program includes a series of survey process simulations. Following the training program, new surveyors complete a minimum of three surveys with a preceptor in the field. As part of the orientation process, a new surveyor must also pass the Surveyor Certification Examination. This 150-question test assesses surveyor competence in standards interpretation, survey process, critical thinking, performance improvement, laptop technology, interpersonal skills, and knowledge of the health care field. Surveyors who fail the examination are not able to survey independently until they have passed the exam. Surveyors who fail to pass the exam after three opportunities have their employment with The Joint Commission terminated. Surveyors must pass a re-certification examination every five years.

California Board of Pharmacy – Joint Commission Request for Continued Recognition Under Business and Professions Code 4127.1

Continuing/ongoing surveyor education includes an annual on-site training conference each January, designed to provide updates and revisions to standards and survey process for the upcoming year. In addition, each surveyor participates in a quarterly educational conference call facilitated by the Home Care Field Director. Every other week, surveyors receive an email addressing topics of interest, including standards interpretation, survey process updates, etc. Finally, all surveyors receive official newsletters from The Joint Commission, which provide updates on new standards and policy changes.

In an effort to ensure ongoing competency, all surveyors receive an annual performance evaluation based upon (1) observations by their supervisor; (2) questionnaires completed by surveyed organizations; (3) trended analysis of survey reports; and (4) peer surveyor evaluations.

4. Acceptance by major California payors: Recognition of the accrediting agency by at least one California healthcare payor (e.g. HMOs, PPOs, PBGH, CalPERS)

Joint Commission accreditation is recognized by several California payor organizations. For example, Blue Shield of California recognizes Joint Commission accreditation for several facility types including acute care hospitals, psychiatric hospitals, ambulatory surgery centers, laboratories, skilled nursing facilities and home health agencies.

5. Unannounced inspection of California accredited sites: The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice. Submit a list of compounding pharmacies accredited by the Joint Commission during the past 12 months.

Pharmacies subject to these regulations are accredited under The Joint Commission's Comprehensive Accreditation Manual for Home Care – Pharmacy standards. A list of organizations currently accredited under this program, along with the date of the most recent full survey, was provided to the Board on June 28, 2010. A copy of that file is attached for your reference.

6. Board access to accreditor's report on individual pharmacies.

Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. However, should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once an authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.

California Board of Pharmacy – Joint Commission Request for Continued Recognition Under Business and Professions Code 4127.1

7. Length of time the accrediting agency has been operating as an accrediting agency.

The Joint Commission has been in operation as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.

8. Ability to accredit out-of-state pharmacies: Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

The Joint Commission can and does accredit pharmacies throughout the United States.

Joint Commission Response to Questions Posed by the California Board of Pharmacy Pharmacies Performing Sterile Compounding September 28, 2010

Are Joint Commission surveyors aware and trained on California's compounding regulations and would they be able to determine if the pharmacy is compliant?

Currently, The Joint Commission's approach to assessing compliance with state law and regulation involves engaging pharmacy staff to determine what the applicable laws and regulations are for a given process. For example, when observing sterile compounding activities, the Joint Commission surveyor would typically ask questions such as "what does the state require in terms of personnel protective equipment when compounding those particular products?" We would expect the pharmacy personnel to describe the state requirement and/or be able to obtain the information.

The Joint Commission is fortunate to have three (3) surveyors who are California-based pharmacists. We are confident that these particular surveyors, when assigned to survey a California compounding pharmacy, have first-hand knowledge of California regulations. However, The Joint Commission is committed to addressing the Board's concern in this area by proactively providing the applicable Board of Pharmacy regulations to each surveyor when assigned to a California compounding pharmacy survey. We will make this information available via a web-based surveyor portal that must be reviewed by each surveyor prior to commencing a survey. We believe that this revised process will better educate all Joint Commission surveyors as to the unique requirements of the CA Board of Pharmacy.

Are Joint Commission surveys conducted by pharmacists? If they are conducted by non-pharmacists, e.g. nurses, will the nurse be competent to evaluate the pharmacy assuring compliance to California's compounding regulations?

As described above, The Joint Commission employs six (6) pharmacist surveyors, with three based in California. This increases the likelihood that a pharmacist will be assigned to pharmacies subject to the Board's jurisdiction. In addition, as indicated in our original submission, nurses with considerable infusion experience may also be assigned to survey pharmacies. However, given the Board's stated preference to have pharmacists perform the surveys, The Joint Commission will commit to making every effort to assign a pharmacist to the survey of California compounding pharmacies subject to the Board's regulations.

How can The Joint Commission assure that accredited pharmacies are in compliance with California rules and regulations pertaining to sterile compounding and are continuously maintaining adherence to Joint Commission Standards? Does the Joint Commission require a self-assessment to be submitted during the accreditation period?

There are a number of mechanisms The Joint Commission employs to promote continuous compliance with standards. First, we require all pharmacies to perform a Periodic Performance Review (PPR). The PPR tool permits organizations to evaluate compliance with all Joint Commission standards. For every noncompliant standard, the organization must identify how it plans to come into compliance with the requirement(s). The evaluation and plan of action must be completed electronically and transmitted to The Joint Commission annually. Following receipt of the evaluation and plan of action, and if requested by the organization, staff from The Joint Commission's Standards Interpretation Group will schedule a telephone call with the pharmacy to discuss and agree upon an acceptable plan of action.

Another concept that promotes continuous compliance is The Joint Commission's unannounced survey process. The vast majority of accreditation surveys are conducted with no prior notice to the pharmacy; therefore, the pharmacy must be continuously prepared to demonstrate compliance with the standards. In addition, the unannounced surveys are conducted during a broad window – starting as early as 18 months from the conclusion of the previous survey. Finally, pharmacies are subject to “for cause” surveys at any time during the accreditation period.

Would there be any objections to having The Joint Commission notify the Board of any serious noncompliance issues that the Board would need to follow up with an inspection?

The Joint Commission already works with state and federal regulatory agencies regarding the disclosure of serious patient safety and quality issues uncovered during an accreditation survey. Joint Commission surveyors immediately notify Joint Commission leadership if they identify any condition they believe poses a serious threat to public or patient health or safety. The president of The Joint Commission can then issue an expedited Preliminary Denial of Accreditation decision based on the threat. All appropriate federal and state governmental authorities are immediately informed of this decision and the findings that led to this action.

The Joint Commission would also notify the CA Board of Pharmacy immediately in the event a pharmacy received an adverse accreditation decision such as Accreditation with Follow-up, Contingent Accreditation and Preliminary Denial of Accreditation. In addition to this notification, the Joint Commission publicly discloses any standards areas with requirements for improvement that contributed to the adverse accreditation decision.

THE JOINT COMMISSION
JOB DESCRIPTION

Date: May 2010

Position: Surveyor

Department: Accreditation and
Certification Operations

Supervisor: Field Director

GENERAL SUMMARY

Under general supervision, surveys health care organizations throughout the United States; Applies systems analysis skills and inductive reasoning skills to determine a health care organizations' degree of compliance with applicable standards and functionality of care delivery systems. Engages health care organization staff in interactive dialogues on standards based issues in health care in order to assess compliance and to identify opportunities for improving compliance; Prepares management reports that clearly link individual standards deficiencies with potential systems vulnerabilities and related organization risk points. Effectively communicates this information to health care organization leadership in a constructive and collegial style. Participates in other Joint Commission activities as assigned.

PRINCIPAL DUTIES AND RESPONSIBILITIES

1. Conducts a thorough evaluation of assigned services and programs that meet accreditation eligibility criteria. Reviews and evaluates pre-survey information and conducts all pre-survey activities. Using organization-specific information, selects patient records based upon an evaluation of priority focus areas. Using patient experiences as guides and discussion tools:
 - Conducts analysis of care delivery systems.
 - Evaluates patient care environments to assess health care organizations' operations and standards compliance.
 - Interviews staff and patients to determine health care organizations' level of compliance with standards.
2. In response to patient-centered evaluation activities, analyzes documents, such as policies, procedures, meeting minutes, clinical standards, protocols, patient records, employee records, committee reports, etc. to assess the level of compliance with Joint Commission standards, implementation of policies, evidence of performance improvement, and quality and safety of care.
3. Using established survey process:
 - Participates in and/or conducts all required on-site activities.
 - Documents all observations in a complete and accurate manner utilizing survey technology. Provides adequate documentation to guide health care organization

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- improvement activities. Provides comprehensive rationale for observations. Links each observation to potential system-level vulnerabilities and opportunities for organizational improvements in patient care and safety. Reports survey findings in a complete, accurate, and timely manner.
4. Interprets and explains the intent of standards to the organization's personnel in a constructive, sensitive, and professional manner. Seeks assistance from Central Office when appropriate.
 5. Through interactive evaluation sessions consults with staff on high profile issues in health care. Offers relevant consultation where improvement is needed.
 6. Maintains current knowledge of Joint Commission standards, policies and procedures. Maintains current knowledge in professional field of expertise. Demonstrates knowledge of state and federal regulations pertinent to the survey.
 7. Completes peer evaluations.
 8. For surveyors cross trained to conduct the LSC Specialist role, maintains current knowledge of Joint Commission Environment of Care standards and NFPA Life Safety Code[®] (LSC) requirements over which they have review responsibility. Demonstrates knowledge of current federal regulations pertinent to the Environment of Care standards and LSC requirements that are evaluated.
 9. Completes staff development programs.
 10. May perform other duties as assigned, including, but not limited to:
 - Participate in special projects.
 - Assist in developing, writing and testing standards, scoring guidelines and the survey process, and provide recommendations for improvement.
 - Assist the Central Office in responding to standards interpretation questions from the field.
 - Assist the Central Office in analysis of organization periodic performance reviews, evidence of standards compliance reports; complaints; and Medicare out-of-compliance reports.
 - Serve on corporate committees, such as the Surveyor Advisory Committee.
 - Serve as team leader when assigned to a team.
 - Serve as faculty for surveyor education and/or field education programs.
 - Receive training and conduct surveys across programs and settings.
 - Serve as preceptor for surveyors.
 - Serve as mentor for on-going surveyor development.

KNOWLEDGE, SKILLS AND ABILITIES

Education:

- Physicians must have a degree of Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.).
- Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline.
- Administrators must have a Master's degree in a health-related field.
- Medical Technologists must have a Master's degree in a related discipline.
- Pharmacists must have a Doctor of Pharmacy degree (Pharm.D.) or equivalent.
- Respiratory Care Practitioners must have a Bachelor's degree; a Master's degree in a related discipline is preferred.
- Social Workers must have a Master's Degree in Social Work.
- Psychologists must have a Psy.D. or Ph.D. in clinical psychology or a related psychological specialty.
- Other health care practitioners must have an advanced degree (Master's or Doctor's) in their related field.
- For surveyors who are cross trained to conduct the LSC Specialist role, must have successfully completed the LSC Specialist training module.

Certification/Licensure (at time of hire):

1. Current professional licensure in related disciplines is required (when required by law) at time of hire.
2. Physicians must be Board Certified at time of hire.
3. Applicants have no history of disciplinary action(s) relative to current or previous professional license, provided such adverse action did not result solely from an individual's health status.
4. Surveyors must obtain and maintain Joint Commission surveyor certification.
5. Medical Technologists must be registered with a nationally accredited organization.

General Knowledge and Experience:

1. Five years of recent experience, including 3 years of direct clinical experience in the appropriate health care setting(s), and 2 years of senior management experience. Recent experience as a consultant to health care organizations may be considered.

2. Contemporary knowledge of and experience in health care operations, clinical practice, use of performance improvement methods to assess organizational performance, and current research and trends relative to health care practices.
3. Experience in an accredited health care organization is preferred.
4. Knowledge of Joint Commission standards and direct involvement with a minimum of two Joint Commission surveys.

Specialized Knowledge and Experience:

1. Surveyors in the Hospital Accreditation Program must have knowledge or experience in various components of a hospital and health care system (i.e., medical staff, quality improvement, medical records, infection control). Additional experience in other health care settings is preferred.
2. Medical Technologists must have experience working in three or more technical specialties (i.e., chemistry, microbiology, blood bank) and experience in settings of multiple sizes, as well as at least 5 years of laboratory management experience.
3. Hospital Administrators with the designation of FACHE (Fellow, American College of Healthcare Executives) are preferred.
4. Administrators in long term care must have a minimum of 5 years experience as a long term care facility administrator or progressive clinical leadership and have a Nursing Home Administrator license (NHA).
5. Nurses in long term care must have a minimum of 5 years experience of progressive organization-wide long term care nursing leadership. A Nursing Home Administrator license (NHA) is preferred. Additional background in hospital nursing leadership is desirable.
6. Surveyors in the Ambulatory program must have at least 5 years experience in an ambulatory care setting. Experience in organizations having multiple services and multiple settings is preferred.
7. Registered Respiratory Therapist surveyors must have 3-5 years experience in home care respiratory therapy practice, including at least 2 years of management experience. Experience must include working for a home medical equipment provider with experience in a variety of durable medical equipment and oxygen delivery systems.
8. It is preferred that surveyors in home care also have recent experience in at least two programs (i.e. hospital, long term care) or settings (i.e., hospice, private duty nursing, Medicare certified agencies, or infusion therapy company).

9. Surveyors in Behavioral Health Care (BHC) must have experience in at least two BHC settings and two different age or disability populations.

Critical Thinking Skills:

1. Ability to research, collect, organize, interpret and communicate a large volume of information from multiple sources (i.e., documentation, observation, interviews) to assess the degree of compliance with Joint Commission standards.
2. Ability to differentiate and assess the adequacy of alternative/innovative approaches to standards compliance, consistent with survey policy and protocols.
3. Ability to analyze and synthesize survey findings to provide conclusions, recommendations and educational opportunities.
4. Ability to connect findings, observations and interviews into a comprehensive analysis of the organization's care delivery systems.

Interpersonal Skills:

1. Sensitive to and respectful of all internal and external customers.
2. Open to inquiry and exchange.
3. Responsive to verbal and nonverbal communication cues.
4. Multi-cultural sensitivity.

Problem Solving Skills:

1. Independent decision-making skills to direct and effectively manage the survey process.
2. Ability to objectively assess organization performance.
3. Ability to openly discuss and resolve conflicts/controversy.
4. Ability to seek assistance when appropriate to make decisions, resolve conflicts and/or achieve consensus.

Interviewing Skills:

1. Ability to elicit information through sensitive, appropriate use of open-ended questions and active listening.

2. Ability to explore information through effective use of follow-up questioning.

Teamwork Skills:

1. Behavior consistent with Joint Commission values (i.e., Quality, Respect, Integrity, Courtesy, Teamwork, Recognition, Improvement, Empowerment and Responsiveness).
2. Dependability, including delivering on commitments, assuming appropriate share of all work, being prepared, and adhering to schedules.
3. Candor, including sharing one's own views, encouraging others to share their views, and being willing to offer and receive constructive feedback.
4. Professionalism, including appearance and demeanor.

Organizational Skills:

1. Independently organize work into a smooth flow and to be flexible as necessitated by unique circumstances.
2. Demonstrate effective time management skills.
3. Coordinate activities involving other people.

Written and Verbal Communication Skills:

1. Ability to make presentations and produce written materials which are accurate, clear, concise, complete, well organized, understandable by others, and responsive to the needs of the customer.
2. Ability to use a computer or similar technology.

Physical Abilities:

1. Must be able to lift 25 pounds.
2. Must be able to climb stairs and ladders.
3. Must be able to travel 100% of work time.
4. Must be able to work in settings in which infectious diseases are present.

Availability:

1. Participation in up to one week of corporate orientation and education upon hire.
2. Completion of up to three surveys with a preceptor in order to demonstrate an understanding of the Joint Commission's standards and their interpretation, survey process, survey technology, presentation techniques, general policies and procedures, and organization structure.
3. Ongoing participation in continuing education activities, including those sponsored by the Joint Commission, (i.e., Annual Invitational Training Conference, teleconferences, self-directed learning activities, distance learning programs, and special conferences).
4. Must be able to meet one of the following availability requirements depending upon employment status:
 - Full time – available 52 weeks/year less vacation, personal, and holiday time
 - Part time – 2 or 3 calendar weeks per month
 - Intermittent – one calendar week per month
5. Weekend travel may be required.

This job description is intended to describe the general nature and level of work performed by an employee assigned to this position. The description is not an exhaustive list of all duties, responsibilities, knowledge, skills and abilities, and working conditions associated with this position. All requirements are subject to possible modification and reasonably accommodate individuals with disabilities.

California Compounding Pharmacy Crosswalk

California Code of Regulations to 2010 Joint Commission Standards & EPs

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Compounding in Licensed Pharmacies.			
§1735.			
§1735. Compounding in Licensed Pharmacies.			
§1735.(a)		LD.04.01.01	The organization complies with law and regulation.
(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		MM.05.01.01	A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.
		EP 1	For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.
		PC.02.01.03	The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.
		EP 1	Prior to providing care, the organization obtains or renews orders (verbal or written) from a licensed independent practitioner in accordance with professional standards of practice and law and regulation.
		EP 4	The organization reviews orders and prescriptions for appropriateness and accuracy before providing care, treatment, or services.
§1735.(a)(1)		LD.04.01.01	The organization complies with law and regulation.
(1) Altering the dosage form or delivery system of a drug		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 2	The organization manages the implementation of policies and procedures.
§1735.(a)(2)		LD.04.01.01	The organization complies with law and regulation.
(2) Altering the strength of a drug		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

CCR Number §1735.(a)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.(a)(3)</p> <p>(3) Combining components or active ingredients</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.(a)(4)</p> <p>(4) Preparing a drug product from chemicals or bulk drug substances</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.(b)</p> <p>(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.(c)</p> <p>(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.(d)</p> <p>(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number §1735.(d)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 2	The organization manages the implementation of policies and procedures.

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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Compounding Definitions.

§1735.1.	
§1735.1. Compounding Definitions.	

§1735.1.(a)	LD.04.01.01 The organization complies with law and regulation.
(a) "Integrity" means retention of potency until the expiration date noted on the label.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 2 The organization manages the implementation of policies and procedures.
	MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.
	EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.

§1735.1.(b)	LD.04.01.01 The organization complies with law and regulation.
(b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 2 The organization manages the implementation of policies and procedures.

§1735.1.(c)	LD.04.01.01 The organization complies with law and regulation.
(c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 2 The organization manages the implementation of policies and procedures.

§1735.1.(d)	LD.04.01.01 The organization complies with law and regulation.
(d) "Strength" means amount of active ingredient per unit of a compounded drug product.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 2 The organization manages the implementation of policies and procedures.

CCR Number §1735.2.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Compounding Limitations and Requirements.			
§1735.2. §1735.2. Compounding Limitations and Requirements.			
§1735.2.(a) (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.	LD.04.01.01 The organization complies with law and regulation. EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations. LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services. EP 2 The organization manages the implementation of policies and procedures. MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization. EP 1 For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.		
§1735.2.(b) (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.	LD.04.01.01 The organization complies with law and regulation. EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations. LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services. EP 2 The organization manages the implementation of policies and procedures. MM.03.01.01 The organization safely stores medications. EP 7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.		
§1735.2.(c) (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:	LD.04.01.01 The organization complies with law and regulation. EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
§1735.2.(c)(1) (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and	LD.04.01.01 The organization complies with law and regulation. EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations. MM.05.01.11 The organization safely dispenses medications. EP 1 The organization dispenses quantities of medications that are consistent with patient needs.		

CCR Number §1735.2.(c)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1735.2.(c)(2) (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.05.01.11 The organization safely dispenses medications.</p> <p>EP 1 The organization dispenses quantities of medications that are consistent with patient needs.</p>
§1735.2.(c)(3) (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
§1735.2.(d) (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.2.(d)(1) (1) Active ingredients to be used.		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.2.(d)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1735.2.(d)(2)</p> <p>(2) Inactive ingredients to be used.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1735.2.(d)(3)</p> <p>(3) Process and/or procedure used to prepare the drug.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 1 When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.</p> <p>EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</p> <p>EP 3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)</p> <p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p>		
<p>§1735.2.(d)(4)</p> <p>(4) Quality reviews required at each step in preparation of the drug.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		

CCR Number §1735.2.(d)(4)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.2.(d)(5)</p> <p>(5) Post-compounding process or procedures required, if any.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)</p>	
<p>§1735.2.(d)(6)</p> <p>(6) Expiration dating requirements.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p>	

CCR Number §1735.2.(d)(6)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</p>			
<p>§1735.2.(e)</p> <p>(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p>		
	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p>		
	<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>		
	<p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.</p>			
<p>EP 1 For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.</p>			
<p>§1735.2.(f)</p> <p>(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.</p>	<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p>		
	<p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p>		
	<p>MM.05.01.07 The organization safely prepares medications.</p>		
	<p>EP 1 When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.</p>		
	<p>EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</p>		
<p>EP 3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)</p>			
<p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p>			

CCR Number §1735.2.(f)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.	<p>EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> <p>EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.</p>
§1735.2.(g) (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.		LD.04.01.01 The organization complies with law and regulation.	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p> <p>EP 8 All expired, damaged, and/or contaminated medications are removed from patient care areas and stored separately from medications available for administration.</p>
§1735.2.(h) (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.		LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.	<p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p> <p>EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</p>
§1735.2.(i) (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.		HR.01.03.01 Staff are supervised effectively.	<p>EP 1 Supervisors understand the care, treatment, or services provided by staff under their supervision.</p> <p>EP 2 Supervisors understand the responsibilities of staff under their supervision.</p> <p>EP 3 Supervisors have clinical and supervisory experience in accordance with law and regulation and organization policy.</p>

CCR Number §1735.2.(i)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		HR.01.06.01	Staff are competent to perform their responsibilities.
		EP 1	The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.
		EP 2	The organization uses assessment methods to determine the individual's competence in the skills being assessed.
		EP 3	An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.
		EP 5	Staff competence is initially assessed and documented as part of orientation.
		EP 6	Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.
		EP 14	Technical staff are competent to deliver and set up equipment, provide services, and train patients and caregivers.
		EP 15	The organization takes action when a staff member's competence does not meet expectations.
		EP 16	The organization maintains copies of competency assessments for personnel who provide services.
		MM.03.01.01	The organization safely stores medications.
		EP 1	The organization stores only approved medications and medications selected by the organization. (See also MM.02.01.01, EP 4)
		EP 2	The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.
		EP 3	The organization stores controlled (scheduled) medications to prevent diversion, in accordance with law and regulation.
		MM.05.01.07	The organization safely prepares medications.
		EP 1	When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.
		EP 2	Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.
		EP 3	During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)
		EP 4	The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.

CCR Number §1735.2.(i)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.	<p>EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> <p>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p> <p>EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</p> <p>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p> <p>EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</p> <p>EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.</p> <p>EP 7 When preparing individualized medications for multiple patients, the label also includes the following: The patient's name.</p> <p>EP 9 When preparing individualized medications for multiple patients, the label also includes the following: Directions for use and applicable accessory and cautionary instructions.</p> <p>EP 10 When an individualized medication(s) is prepared by someone other than the person administering the medication, the label includes the following: The patient's name.</p> <p>EP 12 When an individualized medication(s) is prepared by someone other than the person administering the medication, the label includes the following: Directions for use and applicable accessory and cautionary instructions.</p>
§1735.2.(j)	(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 01/10.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment	HR.01.06.01 Staff are competent to perform their responsibilities.	<p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1735.2.(j)	is to promote compliance through self-examination and education.	LD.04.01.01	The organization complies with law and regulation.
		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

CCR Number §1735.3.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Records of Compounded Drug Products.			
§1735.3. §1735.3. Records of Compounded Drug Products.			
§1735.3.(a)	LD.04.01.01 The organization complies with law and regulation.		
(a) For each compounded drug product, the pharmacy records shall include:	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
§1735.3.(a)(1)	LD.04.01.01 The organization complies with law and regulation.		
(1) The master formula record.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
§1735.3.(a)(2)	LD.04.01.01 The organization complies with law and regulation.		
(2) The date the drug product was compounded.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
§1735.3.(a)(3)	LD.04.01.01 The organization complies with law and regulation.		
(3) The identity of the pharmacy personnel who compounded the drug product.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		

CCR Number §1735.3.(a)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.3.(a)(4)</p> <p>(4) The identity of the pharmacist reviewing the final drug product.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.3.(a)(5)</p> <p>(5) The quantity of each component used in compounding the drug product.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.3.(a)(6)</p> <p>(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1735.3.(a)(6)		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.3.(a)(7)	(7) The equipment used in compounding the drug product.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.3.(a)(8)	(8) A pharmacy assigned reference or lot number for the compounded drug product.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.3.(a)(9)	(9) The expiration date of the final compounded drug product.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number §1735.3.(a)(9)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p>	
<p>§1735.3.(a)(10)</p> <p>(10) The quantity or amount of drug product compounded.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.3.(b)</p> <p>(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1735.3.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>MM.01.01.03 The organization safely manages high-alert and hazardous medications.</p> <p>EP 1 The organization identifies, in writing, its high-alert and hazardous medications. * Footnote *: For a list of high-alert medications, see http://www.ismp.org. For a list of hazardous medications, see http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html.</p> <p>EP 2 The organization has a process for managing high-alert and hazardous medications. (See also MM.03.01.01, EP 9)</p> <p>EP 3 The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)</p> <p>MM.02.01.01 The organization selects and procures medications.</p> <p>EP 2 The organization develops and approves criteria for selecting medications, which include the following: <ul style="list-style-type: none"> - Indications for use (See also MM.05.01.01, EP 10) - Effectiveness - Drug interactions - Potential for errors and abuse - Adverse drug events - Sentinel event advisories - Other risks - Costs </p> <p>EP 4 The organization maintains a written list of medications, including strength and dosage, for dispensing and administering. (See also MM.03.01.01, EP 1) Note: In some settings, the term "formulary" is used instead of "list of medications available for use." The terms are synonymous.</p> <p>EP 6 The organization standardizes and limits the number of drug concentrations.</p> <p>EP 7 The organization has a process to select and procure medications that are not on its list of medications.</p> <p>EP 8 The organization implements the process to select and procure medications that are not on its medication list.</p> <p>EP 9 Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p> <p>EP 4 The organization has a written process addressing the control of the medication between receipt by the organization and delivery to or administration at the designated site.</p>
§1735.3.(c)	(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number §1735.3.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		MM.02.01.01	<p>The organization selects and procures medications.</p> <p>EP 2 The organization develops and approves criteria for selecting medications, which include the following:</p> <ul style="list-style-type: none"> - Indications for use (See also MM.05.01.01, EP 10) - Effectiveness - Drug interactions - Potential for errors and abuse - Adverse drug events - Sentinel event advisories - Other risks - Costs
§1735.3.(d)		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.4.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Labeling of Compounded Drug Products.			
§1735.4. §1735.4. Labeling of Compounded Drug Products.			
§1735.4.(a) (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> <p>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p> <p>EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</p> <p>EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.</p>		
§1735.4.(b) (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 1 When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p>		

CCR Number §1735.4.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1735.4.(c)	(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.	LD.04.01.01	<p data-bbox="1094 115 1675 142">The organization complies with law and regulation.</p> <p data-bbox="961 175 1995 224">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 245 2018 326">MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p>
			<p data-bbox="961 354 2007 500">EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> <p data-bbox="961 521 1948 570">EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p> <p data-bbox="961 591 1980 639">EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</p> <p data-bbox="961 660 2011 709">EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p> <p data-bbox="961 730 2011 779">EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</p> <p data-bbox="961 800 1990 849">EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.</p>

CCR Number §1735.5.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Compounding Policies and Procedures.			
§1735.5. §1735.5. Compounding Policies and Procedures.			<p data-bbox="926 277 2041 337">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="926 337 2041 412">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="926 412 2041 487">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="926 487 2041 634">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="926 634 2041 683">EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.5.(a) (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.			<p data-bbox="926 683 2041 743">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="926 743 2041 818">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="926 818 2041 893">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="926 893 2041 1040">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="926 1040 2041 1081">EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.5.(b) (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.			<p data-bbox="926 1081 2041 1141">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="926 1141 2041 1216">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="926 1216 2041 1291">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="926 1291 2041 1438">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="926 1438 2041 1482">EP 2 The organization manages the implementation of policies and procedures.</p>
§1735.5.(c) (c) The policy and procedure manual shall include the following			<p data-bbox="926 1442 2041 1502">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="926 1502 2041 1576">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="926 1576 2041 1624">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="926 1624 2041 1624">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="926 1624 2041 1624">EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.5.(c)(1)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1735.5.(c)(1)</p> <p>(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.5.(c)(2)</p> <p>(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</p> <p>EP 1 The organization has a written policy describing how it will retrieve and handle medications within the organization that are recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration.</p> <p>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</p> <p>EP 3 When a medication is recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration, the organization notifies the prescribers and those who dispense or administer the medication.</p> <p>EP 4 When required by law and regulation or organization policy, the organization informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration.</p>	

CCR Number §1735.5.(c)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards		
<p>(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.</p>		<p>HR.01.04.01 The organization provides orientation to staff.</p> <p>EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3) Note: Key safety content may include specific processes and procedures related to the provision of care, treatment, or services; the environment of care; and infection control.</p> <p>EP 2 The organization orients its staff to the key safety content before staff provides care, treatment, or services. Completion of this orientation is documented. (See also IC.01.05.01, EP 6)</p> <p>EP 3 The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.</p> <p>EP 4 The organization orients staff on the following: Their specific job duties, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7; RI.01.01.01, EP 8)</p>			
				<p>HR.01.05.03 Staff participate in ongoing education and training.</p>	
				<p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>	
				<p>EP 2 The organization's education and training comply with law and regulation.</p>	
		<p>EP 4 Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</p>			
		<p>EP 5 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. (See also PC.01.02.09, EP 3)</p>			
		<p>EP 7 Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.</p>			
		<p>IC.01.02.01 Organization leaders allocate needed resources for infection prevention and control activities.</p>			
		<p>EP 3 The organization provides equipment and supplies to support infection prevention and control activities.</p>			
		<p>IC.01.04.01 Based on the identified risks, the organization sets goals to minimize the possibility of spreading infections. Note: See NPSG.07.01.01 for hand hygiene guidelines.</p>			
		<p>EP 4 The organization's written infection prevention and control goals include the following: Limiting the spread of infections associated with the use of medical equipment, devices, and supplies.</p>			

CCR Number §1735.5.(c)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>IC.02.02.01 The organization reduces the risk of infections associated with medical equipment, devices, and supplies.</p> <p>EP 1 The organization implements infection prevention and control activities when doing the following: Cleaning and performing disinfection of medical supplies and devices. * (See also EQ.01.05.01, Eps 3 and 4) Note: Disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing disinfection of medical equipment, devices, and supplies, refer to the Web site of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/ncidod/dhqp/sterile.html (Sterilization and Disinfection in Healthcare Settings).</p> <p>EP 3 The organization implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies in accordance with law and regulation.</p> <p>EP 4 The organization implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies. (See also EQ.01.01.01, EP 9 and EQ.01.05.01, EPs 1-5)</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.5.(c)(4)</p> <p>(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1735.5.(c)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.		LD.04.01.01	The organization complies with law and regulation.
		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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Compounding Facilities and Equipment.

§1735.6.	
§1735.6. Compounding Facilities and Equipment.	

§1735.6.(a)	EC.02.06.01 The organization establishes and maintains a safe, functional environment.
(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.	EP 1 Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.
	EP 11 Lighting is suitable for care, treatment, or services.
	EP 13 The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, or services provided.
	EP 32 The organization provides space for staff to perform their required work safely and accurately.
	LD.04.01.01 The organization complies with law and regulation.
	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
	EP 2 The organization manages the implementation of policies and procedures.

§1735.6.(b)	EC.04.01.01 The organization collects information to monitor conditions in the environment.
(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.	EP 17 The organization identifies, reports within the organization, and investigates equipment management problems, failures, and use errors for equipment provided to the patient.
	LD.04.01.01 The organization complies with law and regulation.
	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.
	EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.

CCR Number §1735.6.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
EP 2 The organization manages the implementation of policies and procedures.			
§1735.6.(c)	LD.04.01.01 The organization complies with law and regulation.		
(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.			
EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.			
EP 2 The organization manages the implementation of policies and procedures.			

CCR Number §1735.7.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Training of Compounding Staff.			
§1735.7.			
§1735.7. Training of Compounding Staff.			
§1735.7.(a)	HR.01.04.01 The organization provides orientation to staff.		
(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.	<p>EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3) Note: Key safety content may include specific processes and procedures related to the provision of care, treatment, or services; the environment of care; and infection control.</p>		
	<p>EP 2 The organization orients its staff to the key safety content before staff provides care, treatment, or services. Completion of this orientation is documented. (See also IC.01.05.01, EP 6)</p>		
	<p>EP 3 The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.</p>		
	<p>EP 4 The organization orients staff on the following: Their specific job duties, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7; RI.01.01.01, EP 8)</p>		
	HR.01.05.03 Staff participate in ongoing education and training.		
	<p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>		
	<p>EP 2 The organization's education and training comply with law and regulation.</p>		
	<p>EP 4 Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</p>		
	<p>EP 5 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. (See also PC.01.02.09, EP 3)</p>		
	<p>EP 7 Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.</p>		
	HR.01.06.01 Staff are competent to perform their responsibilities.		
	<p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p>		
	<p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p>		
	<p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p>		
	<p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p>		

CCR Number §1735.7(a)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 14 Technical staff are competent to deliver and set up equipment, provide services, and train patients and caregivers.</p> <p>EP 15 The organization takes action when a staff member's competence does not meet expectations.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
<p>§1735.7.(b)</p> <p>(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.</p>		<p>HR.01.05.03 Staff participate in ongoing education and training.</p>	<p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>EP 2 The organization's education and training comply with law and regulation.</p> <p>EP 4 Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</p> <p>EP 5 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. (See also PC.01.02.09, EP 3)</p> <p>EP 7 Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.</p>
		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p>	<p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 14 Technical staff are competent to deliver and set up equipment, provide services, and train patients and caregivers.</p> <p>EP 15 The organization takes action when a staff member's competence does not meet expectations.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>

CCR Number §1735.7.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1735.7.(c)</p> <p>(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.</p>		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number §1735.8.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Compounding Quality Assurance.			
§1735.8. §1735.8. Compounding Quality Assurance.			
<p>§1735.8.(a)</p> <p>(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>LD.04.04.01 Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)</p> <p>EP 1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.</p> <p>EP 2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)</p> <p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p>		

CCR Number §1735.8.(a)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p>
			<p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
			<p>PI.01.01.01 The organization collects data to monitor its performance.</p>
			<p>EP 1 The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)</p>
			<p>EP 2 The organization identifies the frequency for data collection.</p>
			<p>EP 3 The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)</p>
			<p>PI.02.01.01 The organization compiles and analyzes data.</p>
			<p>EP 1 The organization compiles data in usable formats.</p>
			<p>EP 2 The organization identifies the frequency of data analysis.</p>
			<p>EP 4 The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.</p>
			<p>EP 5 The organization compares data with external sources, when available.</p>
			<p>EP 8 The organization uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5; PI.03.01.01, EP 1)</p>
			<p>EP 10 For hospices that elect to use The Joint Commission deemed status option: The hospice uses the data collected to monitor the effectiveness and safety of services and the quality of care.</p>
§1735.8.(b)			<p>LD.04.01.01 The organization complies with law and regulation.</p>
(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.			<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
			<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p>
			<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>
			<p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.8.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.04.01 Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)</p> <p>EP 1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.</p> <p>EP 2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)</p>	<p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
<p>§1735.8.(c)</p> <p>(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.8.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.04.01 Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)</p> <p>EP 1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.</p> <p>EP 2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)</p>	<p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
<p>§1735.8.(d)</p> <p>(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1735.8.(d)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		LD.04.04.01	Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)
		EP 1	Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.
		EP 2	Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)
		MM.07.01.03	The organization responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
		EP 1	The organization has a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
		EP 2	The organization has a written process addressing prescriber notification in the event of an adverse drug event, significant adverse drug reaction, or medication error.
		EP 3	The organization complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
		EP 5	The organization implements its process for responding to adverse drug events, significant adverse drug reactions, and medication errors.
		MM.08.01.01	The organization evaluates the effectiveness of its medication management processes.
		EP 1	The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)
		EP 2	The organization analyzes data on its medication management processes.
		EP 3	The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.
		EP 4	The organization reviews the literature and other external sources for new technologies and best practices.
		EP 5	Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.
		EP 6	The organization takes action on improvement opportunities identified as priorities for its medication management processes.
		EP 7	The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.
		EP 8	The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.
		EP 10	The long term care pharmacy or consultant pharmacist provides education to the long term care facility regarding the processes to reduce medication errors.

CCR Number §1735.8.(d)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		PI.02.01.01 The organization compiles and analyzes data. EP 4 The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations. EP 8 The organization uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5; PI.03.01.01, EP 1)	
		PI.03.01.01 The organization improves performance. EP 4 The organization takes action when it does not achieve or sustain planned improvements.	

CCR Number §4123.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Compounding Drug for Other Pharmacy for Parenteral Therapy			
§4123.	LD.01.01.01 The organization has a leadership structure.		
§4123. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.	EP 2 Governance identifies those responsible for planning, management, and operational activities.		
	EP 3 Governance identifies those responsible for the provision of care, treatment, or services.		
	LD.01.03.01 Governance is ultimately accountable for the safety and quality of care, treatment, or services.		
	EP 1 Governance defines in writing its responsibilities.		
	EP 6 Governance works with other leaders to annually evaluate the organization's performance in relation to its mission, vision, and goals.		
	LD.04.01.01 The organization complies with law and regulation.		
EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.			
LD.04.03.09 Care, treatment, or services provided through contractual agreement are provided safely and effectively.			
EP 2 The organization describes, in writing, the nature and scope of services provided through contractual agreements.			
EP 3 Designated leaders approve contractual agreements.			
EP 4 Leaders monitor contracted services by establishing expectations for the performance of the contracted services.			
EP 5 Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services. Note: A written description of the expectations can be provided either as part of the written agreement or in addition to it.			
EP 6 Leaders monitor contracted services by evaluating these services in relation to the organization's expectations.			
EP 7 Leaders take steps to improve contracted services that do not meet expectations. Note: Examples of improvement efforts to consider include the following: - Increase monitoring of the contracted services. - Provide consultation or training to the contractor. - Renegotiate the contract terms. - Apply defined penalties. - Terminate the contract.			
EP 8 When contractual agreements are renegotiated or terminated, the organization maintains the continuity of patient care.			

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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§4127.1. Pharmacies that Compound Sterile Injectable Drugs

§4127 LD.04.01.01 The organization complies with law and regulation.

§4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *

Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.

Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

Footnote *: For more information on how to obtain a CLIA certificate, see <http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>.

EP 10 The organization displays all licenses, certificates, and permits to operate in an area accessible to customers and patients.

§4127.1.(a) LD.04.01.01 The organization complies with law and regulation.

§4127.1.(a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *

Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.

Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

Footnote *: For more information on how to obtain a CLIA certificate, see <http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>.

EP 10 The organization displays all licenses, certificates, and permits to operate in an area accessible to customers and patients.

CCR Number §4127.1.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§4127.1.(b)</p> <p>(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p>	<p>EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *</p> <p>Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.</p> <p>Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.</p> <p>Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)</p> <p>Footnote *: For more information on how to obtain a CLIA certificate, see http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf.</p> <p>EP 10 The organization displays all licenses, certificates, and permits to operate in an area accessible to customers and patients.</p>
<p>§4127.1.(c)</p> <p>(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p>	<p>EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *</p> <p>Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.</p> <p>Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.</p> <p>Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)</p> <p>Footnote *: For more information on how to obtain a CLIA certificate, see http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf.</p> <p>EP 10 The organization displays all licenses, certificates, and permits to operate in an area accessible to customers and patients.</p>
<p>§4127.1.(d)</p> <p>(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement</p>			

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.1.(d)	to obtain a license pursuant to this section.		
§4127.1.(e)	(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:		
§4127.1.(e)(1)	(1) The sterile powder was obtained from a manufacturer.		
§4127.1.(e)(2)	(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.		
§4127.1.(f)	(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.		

CCR Number §4127.2.(a)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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§4127.2. Pharmacies that Compound Sterile Injectable Drugs

§4127.2.(a) LD.04.01.01 The organization complies with law and regulation.

§4127.2.(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *

Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.

Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

Footnote *: For more information on how to obtain a CLIA certificate, see <http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>.

§4127.2.(b) LD.04.01.01 The organization complies with law and regulation.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

EP 1 The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission. *

Note 1: For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.

Note 2: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

Note 3: Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

Footnote *: For more information on how to obtain a CLIA certificate, see <http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>.

§4127.2.(b)(1) LD.04.01.01 The organization complies with law and regulation.

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.2.(b)(1)		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§4127.2.(b)(2)	(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07</p> <p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§4127.2.(c)	(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.		
§4127.2.(d)	(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.		

CCR Number §4127.3.(a)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.3. Pharmacies that Compound Sterile Injectable Drugs			
<p>§4127.3.(a)</p> <p>§4127.3.(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.</p>		<p>APR.05.01.01 The organization allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.</p>	<p>EP 1 When requested, the organization provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.</p>
<p>§4127.3.(b)</p> <p>(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.</p>		<p>APR.05.01.01 The organization allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.</p>	<p>EP 1 When requested, the organization provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.</p>
<p>§4127.3.(c)</p> <p>(c)The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.</p>		<p>APR.05.01.01 The organization allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.</p>	<p>EP 1 When requested, the organization provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.</p>
<p>§4127.3.(d)</p> <p>(d)Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.</p>		<p>APR.05.01.01 The organization allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.</p>	<p>EP 1 When requested, the organization provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.4.			
§4127.4. Pharmacies that Compound Sterile Injectable Drugs			
§4127.4.			
<p>§4127.4. Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.</p>			

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.5.			
§4127.5. Pharmacies that Compound Sterile Injectable Drugs			
§4127.5.			
<p>§4127.5. The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).</p>			

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.6.			
§4127.6. Pharmacies that Compound Sterile Injectable Drugs			
§4127.6.			
<p>§4127.6. This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.</p>			

CCR Number §4127.7.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.7. Pharmacies that Compound Sterile Injectable Drugs			
<p>§4127.7.</p> <p>§4127.7. On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:</p>			
§4127.7.(a)		MM.05.01.07 The organization safely prepares medications.	
(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.	EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.		
§4127.7.(b)		MM.05.01.07 The organization safely prepares medications.	
(b) An ISO class 5 cleanroom.	EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.		
§4127.7.(c)		MM.05.01.07 The organization safely prepares medications.	
(c) A barrier isolator that provides an ISO class 5 environment for compounding.	EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.		

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§4127.8.	§4127.8. Pharmacies that Compound Sterile Injectable Drugs		
<p>§4127.8.</p> <p>§4127.8. The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred dollars (\$500) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.</p>			

CCR Number §1751.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Sterile Injectable Compounding; Compounding Area.			
§1751.			
§1751. Sterile Injectable Compounding; Compounding Area.			
§1751.(a)	LD.04.01.01 The organization complies with law and regulation.		
(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
§1751.(b)			
(b) Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:			
§1751.(b)(1)	EC.02.06.01 The organization establishes and maintains a safe, functional environment.		
(1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.	EP 1 Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.		
	EP 13 The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, or services provided.		
	EP 32 The organization provides space for staff to perform their required work safely and accurately.		
	MM.05.01.07 The organization safely prepares medications.		
	EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.		
§1751.(b)(2)	EC.02.06.01 The organization establishes and maintains a safe, functional environment.		
(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.	EP 1 Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.		
	EP 32 The organization provides space for staff to perform their required work safely and accurately.		
§1751.(b)(3)	EC.02.06.01 The organization establishes and maintains a safe, functional environment.		
(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.	EP 1 Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.		
	EP 13 The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, or services provided.		

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.(b)(3)			EP 32 The organization provides space for staff to perform their required work safely and accurately.
§1751.(b)(4)	(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.	EQ.02.01.01	<p>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p> <p>EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.</p> <p>EP 4 The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.</p> <p>EP 5 The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p>
§1751.(b)(5)	(5) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p>
§1751.(b)(6)	(6) A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
§1751.(b)(7)	(7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p>

CCR Number §1751.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.		LD.04.01.01 The organization complies with law and regulation.	
		EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
		MM.05.01.07 The organization safely prepares medications.	
		EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.	
		EP 3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)	
		EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients. [Renumbered]			

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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Policies and Procedures. [Renumbered]

CCR Number §1751.1.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Sterile Injectable Recordkeeping Requirements.			
<p>§1751.1.</p> <p>§1751.1. Sterile Injectable Recordkeeping Requirements.</p>			
<p>§1751.1.(a)</p> <p>(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
<p>§1751.1.(b)</p> <p>(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:</p>			
<p>§1751.1.(b)(1)</p> <p>(1) The training and competency evaluation of employees in sterile product procedures.</p>	<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p>		
	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
<p>§1751.1.(b)(2)</p> <p>(2) Refrigerator and freezer temperatures.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	<p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p>		
<p>§1751.1.(b)(3)</p> <p>(3) Certification of the sterile compounding environment.</p>	<p>EQ.02.01.01 The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p>		

CCR Number §1751.1.(b)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.</p> <p>EP 4 The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.</p> <p>EP 5 The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
§1751.1.(b)(4)			<p>LD.04.01.01 The organization complies with law and regulation.</p>
(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).			<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.1.(b)(5)			<p>LD.04.01.01 The organization complies with law and regulation.</p>
(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.			<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>EP 3 For home health agencies that elect to use The Joint Commission deemed status option: The home health agency has written policies that support its personnel practices and patient care.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 8 All expired, damaged, and/or contaminated medications are removed from patient care areas and stored separately from medications available for administration.</p>

CCR Number §1751.1.(b)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>EP 18 The organization periodically inspects all medication storage areas.</p> <p>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</p> <p>EP 1 The organization has a written policy describing how it will retrieve and handle medications within the organization that are recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration.</p> <p>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</p>	
<p>§1751.1.(b)(6)</p> <p>(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.1.(c)</p> <p>(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
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Sterile Injectable Labeling Requirements.

§1751.2.	
§1751.2. Sterile Injectable Labeling Requirements	

§1751.2.	
In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:	

§1751.2.(a)	LD.04.01.01 The organization complies with law and regulation.
(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

§1751.2.(b)	LD.04.01.01 The organization complies with law and regulation.
(b) Name and concentrations of ingredients contained in the sterile injectable product.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.
	EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.
	EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.

§1751.2.(c)	LD.04.01.01 The organization complies with law and regulation.
(c) Instructions for storage and handling.	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
	MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.
	EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.
	EP 9 When preparing individualized medications for multiple patients, the label also includes the following: Directions for use and applicable accessory and cautionary instructions.

CCR Number §1751.2.(d)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
(d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly."		EC.02.02.01	The organization manages risks related to hazardous materials and waste.
		EP 12	The organization labels hazardous materials and waste. * Labels identify the contents and hazard warnings. Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements.
		LD.04.01.01	The organization complies with law and regulation.
		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

CCR Number §1751.3.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Sterile Injectable Policies and Procedures.			
§1751.3.			
§1751.3. Sterile Injectable Policies and Procedures.			
§1751.3.(a)			
(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:			
§1751.3.(a)(1)	LD.04.01.01 The organization complies with law and regulation.		
(1) Compounding, filling, and labeling of sterile injectable compounds.	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.		
	<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>		
	EP 2 The organization manages the implementation of policies and procedures.		
	MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.		
	<p>EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p>		
	EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.		
	EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).		
	EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.		
	EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.		

CCR Number §1751.3.(a)(1)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p align="center">EP 6 All medications prepared in the organization are correctly labeled with the following: Date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.</p>			
<p>§1751.3.(a)(2)</p> <p>(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p> <p>EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</p>		
<p>§1751.3.(a)(3)</p> <p>(3) Equipment and supplies.</p>	<p>EQ.01.05.01 The organization receives and stores medical equipment and supplies at its site(s).</p> <p>EP 1 The organization designates clearly identified, separate areas for storing each of the following types of equipment: - Obsolete equipment - Equipment requiring maintenance or repair - Dirty equipment - Clean equipment - Patient-ready equipment (See also IC.02.02.01, EP 4)</p> <p>EP 2 The organization stores equipment and supplies in the appropriately designated areas, addressing storage considerations such as expiration dates, temperature requirements, and battery charge requirements. (See also IC.02.02.01, EP 4)</p> <p>EP 3 The organization processes equipment that requires cleaning and disinfecting in a separate area designated for this use. (See also IC.02.02.01, EPs 1 and 4)</p> <p>EP 4 The organization maintains the cleanliness of patient-ready medical equipment. (See also IC.02.02.01, EPs 1 and 4)</p> <p>EP 5 The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)</p>		

CCR Number §1751.3.(a)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>EQ.02.01.01 The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p> <p>EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.</p> <p>EP 2 The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.</p> <p>EP 3 The organization evaluates the performance of devices used for analyzing, measuring, and testing medical equipment, according to the manufacturers' guidelines. The organization documents the performance of these checks.</p> <p>EP 4 The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.</p> <p>EP 5 The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(a)(4)</p> <p>(4) Training of staff in the preparation of sterile injectable products.</p>		<p>HR.01.04.01 The organization provides orientation to staff.</p> <p>EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3) Note: Key safety content may include specific processes and procedures related to the provision of care, treatment, or services; the environment of care; and infection control.</p> <p>EP 2 The organization orients its staff to the key safety content before staff provides care, treatment, or services. Completion of this orientation is documented. (See also IC.01.05.01, EP 6)</p> <p>EP 3 The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.</p>	

CCR Number §1751.3.(a)(4)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p data-bbox="963 118 1955 191">EP 4 The organization orients staff on the following: Their specific job duties, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7; RI.01.01.01, EP 8)</p> <p data-bbox="932 212 1671 237">HR.01.05.03 Staff participate in ongoing education and training.</p> <p data-bbox="963 269 1940 318">EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p data-bbox="963 342 1709 367">EP 2 The organization's education and training comply with law and regulation.</p> <p data-bbox="963 391 1913 440">EP 4 Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</p> <p data-bbox="963 464 2003 513">EP 5 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. (See also PC.01.02.09, EP 3)</p> <p data-bbox="932 529 1671 553">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="963 586 1992 634">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 659 1965 708">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="963 740 1986 854">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="963 878 1717 902">EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.3.(a)(5)	(5) Procedures for handling cytotoxic agents.		<p data-bbox="932 935 1940 959">EC.02.02.01 The organization manages risks related to hazardous materials and waste.</p> <p data-bbox="963 992 1971 1089">EP 1 The organization maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation. (See also IC.02.01.01, EP 6; MM.01.01.03, EP 3)</p> <p data-bbox="963 1114 2007 1162">EP 2 The organization manages hazardous materials and waste from receipt or generation through final use or disposal.</p> <p data-bbox="963 1187 1940 1235">EP 3 The organization has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures.</p> <p data-bbox="963 1260 1940 1308">EP 4 The organization implements its procedures in response to hazardous material and waste spills or exposures.</p> <p data-bbox="963 1333 2007 1382">EP 11 For managing hazardous materials and waste, the organization has the permits, licenses, manifests, and material safety data sheets required by law and regulation.</p>

CCR Number §1751.3.(a)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>EP 12 The organization labels hazardous materials and waste. * Labels identify the contents and hazard warnings. Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.3.(a)(6)	(6) Quality assurance program.		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
			<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>LD.04.04.01 Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)</p> <p>EP 1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.</p> <p>EP 2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)</p> <p>EP 3 Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.</p> <p>EP 4 Performance improvement occurs organization-wide.</p>

CCR Number §1751.3.(a)(6)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p> <p>PI.01.01.01 The organization collects data to monitor its performance.</p> <p>EP 1 The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)</p> <p>EP 2 The organization identifies the frequency for data collection.</p> <p>EP 3 The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)</p>	
§1751.3.(a)(7)	(7) Record keeping requirements.	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
		<p>RC.01.05.01 The organization retains its patient records.</p> <p>EP 1 The retention time of the patient record is determined by its use and organization policy, in accordance with law and regulation.</p>	

CCR Number §1751.3.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.3.(b)</p> <p>(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.</p> <p>EP 1 For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.</p>	
<p>§1751.3.(c)</p> <p>(c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.</p>		<p>EC.02.02.01 The organization manages risks related to hazardous materials and waste.</p> <p>EP 1 The organization maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation. (See also IC.02.01.01, EP 6; MM.01.01.03, EP 3)</p> <p>EP 2 The organization manages hazardous materials and waste from receipt or generation through final use or disposal.</p> <p>EP 3 The organization has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures.</p> <p>EP 4 The organization implements its procedures in response to hazardous material and waste spills or exposures.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1751.3.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>MM.01.01.03 The organization safely manages high-alert and hazardous medications.</p> <p>EP 1 The organization identifies, in writing, its high-alert and hazardous medications. * Footnote *: For a list of high-alert medications, see http://www.ismp.org. For a list of hazardous medications, see http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html.</p> <p>EP 3 The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)</p>	
<p>§1751.3.(d)</p> <p>(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:</p>			
<p>§1751.3.(d)(1)</p> <p>(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(2)</p> <p>(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.</p>		<p>HR.01.04.01 The organization provides orientation to staff.</p> <p>EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3) Note: Key safety content may include specific processes and procedures related to the provision of care, treatment, or services; the environment of care; and infection control.</p>	
		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>EP 2 The organization's education and training comply with law and regulation.</p>	
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number §1751.3.(d)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(3)</p> <p>(3) Policies and procedures must address at least the following:</p>			
<p>§1751.3.(d)(3)(A)</p> <p>(A) Competency evaluation.</p>		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(3)(B)</p> <p>(B) Storage and handling of products and supplies.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number §1751.3.(d)(3)(B)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(3)(C)</p> <p>(C) Storage and delivery of final products.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(3)(D)</p> <p>(D) Process validation.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1751.3.(d)(3)(E)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.3.(d)(3)(E) (E) Personnel access and movement of materials into and near the controlled area.		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</p>
§1751.3.(d)(3)(F) (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p>
§1751.3.(d)(3)(G) (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.		EQ.01.05.01	<p>The organization receives and stores medical equipment and supplies at its site(s).</p> <p>EP 1 The organization designates clearly identified, separate areas for storing each of the following types of equipment: - Obsolete equipment - Equipment requiring maintenance or repair - Dirty equipment - Clean equipment - Patient-ready equipment (See also IC.02.02.01, EP 4)</p>

CCR Number §1751.3.(d)(3)(G)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 3 The organization processes equipment that requires cleaning and disinfecting in a separate area designated for this use. (See also IC.02.02.01, EPs 1 and 4)</p>
			<p>EP 4 The organization maintains the cleanliness of patient-ready medical equipment. (See also IC.02.02.01, EPs 1 and 4)</p>
			<p>EP 5 The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)</p>
			<p>EQ.02.01.01 The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p>
			<p>EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.</p>
			<p>IC.01.05.01 The organization plans for preventing and controlling infections.</p>
			<p>EP 1 When developing infection prevention and control activities, the organization uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus, or, in the absence of both, a review and evaluation of the health care literature.</p>
			<p>IC.02.01.01 The organization implements the infection prevention and control activities it has planned.</p>
			<p>EP 1 The organization implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection. Note: Surveillance activities address processes and/or outcomes.</p>
			<p>EP 2 The organization uses standard precautions, * including the use of personal protective equipment, to reduce the risk of infection. Note: Standard precautions are infection prevention and control measures to protect against possible exposure to infectious agents. These precautions are general and applicable to all patients. Footnote *: For further information regarding standard precautions, refer to the Web site of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/ncidod/dhqp/ (Infection Control in Healthcare Settings).</p>
			<p>IC.02.02.01 The organization reduces the risk of infections associated with medical equipment, devices, and supplies.</p>
			<p>EP 1 The organization implements infection prevention and control activities when doing the following: Cleaning and performing disinfection of medical supplies and devices. * (See also EQ.01.05.01, Eps 3 and 4) Note: Disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing disinfection of medical equipment, devices, and supplies, refer to the Web site of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/ncidod/dhqp/sterile.html (Sterilization and Disinfection in Healthcare Settings).</p>

CCR Number §1751.3.(d)(3)(G)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.3.(d)(3)(H)</p> <p>(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.</p>		<p>EC.02.02.01 The organization manages risks related to hazardous materials and waste.</p> <p>EP 1 The organization maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation. (See also IC.02.01.01, EP 6; MM.01.01.03, EP 3)</p> <p>EP 2 The organization manages hazardous materials and waste from receipt or generation through final use or disposal.</p> <p>EP 3 The organization has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures.</p> <p>EP 4 The organization implements its procedures in response to hazardous material and waste spills or exposures.</p> <p>EP 11 For managing hazardous materials and waste, the organization has the permits, licenses, manifests, and material safety data sheets required by law and regulation.</p> <p>EP 12 The organization labels hazardous materials and waste. * Labels identify the contents and hazard warnings. Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements.</p> <p>IC.02.01.01 The organization implements the infection prevention and control activities it has planned.</p> <p>EP 3 In addition to standard precautions, the organization takes precautions in response to the way suspected or identified infections are spread * within the organization's service setting and community. Footnote *: For further information regarding precautions for the way certain infections are spread (such as contact, droplet, or airborne), refer to the Web site of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/ncidod/dhqp/ (Infection Control in Healthcare Settings).</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.3.(d)(3)(H)		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.3.(d)(3)(I)	(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.3.(d)(3)(J)	(J) Sterilization.	IC.01.02.01	<p>Organization leaders allocate needed resources for infection prevention and control activities.</p> <p>EP 1 The organization provides access to information needed to support infection prevention and control activities. (See also IM.02.02.03, EP 2)</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.3.(d)(3)(K)	§1751.3.(d)(3)(K)	LD.04.01.01	The organization complies with law and regulation.
(K) End-product evaluation and testing.		<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>	
		<p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1751.4.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Facility and Equipment Standards for Sterile Injectable Compounding.			
§1751.4. §1751.4. Facility and Equipment Standards for Sterile Injectable Compounding.			
<p>§1751.4.(a)</p> <p>(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.4.(b)</p> <p>(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.4.(c)</p> <p>(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		

CCR Number §1751.4.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		LD.04.01.11	<p>The organization makes space and equipment available as needed for the provision of care, treatment, or services.</p> <p>EP 2 The arrangement and allocation of space supports safe, efficient, and effective care, treatment, or services.</p> <p>EP 5 The leaders provide for equipment, supplies, and other resources.</p>
<p>§1751.4.(d)</p> <p>(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.</p>		EQ.01.05.01	<p>The organization receives and stores medical equipment and supplies at its site(s).</p> <p>EP 5 The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
<p>§1751.4.(e)</p> <p>(e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.</p>		EQ.02.01.01	<p>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p> <p>EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.</p> <p>EP 5 The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number §1751.4.(e)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
		MM.05.01.07	<p>The organization safely prepares medications.</p> <p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p>

CCR Number §1751.5.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Sterile Injectable Compounding Attire.			
§1751.5.			
§1751.5. Sterile Injectable Compounding Attire.			
§1751.5.(a)	EC.02.02.01 The organization manages risks related to hazardous materials and waste.		
(a) When preparing cytotoxic agents, gowns and gloves shall be worn.	EP 2 The organization manages hazardous materials and waste from receipt or generation through final use or disposal.		
	EP 3 The organization has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures.		
	EP 4 The organization implements its procedures in response to hazardous material and waste spills or exposures.		
	EP 11 For managing hazardous materials and waste, the organization has the permits, licenses, manifests, and material safety data sheets required by law and regulation.		
	EP 12 The organization labels hazardous materials and waste. * Labels identify the contents and hazard warnings. Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements.		
	IC.01.02.01 Organization leaders allocate needed resources for infection prevention and control activities.		
	EP 3 The organization provides equipment and supplies to support infection prevention and control activities.		
	LD.04.01.01 The organization complies with law and regulation.		
	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.		
	EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.		
	EP 2 The organization manages the implementation of policies and procedures.		
§1751.5.(b)	LD.04.01.01 The organization complies with law and regulation.		
(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		

CCR Number §1751.5.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.5.(b)(1)</p> <p>(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.</p>	<p>IC.01.02.01 Organization leaders allocate needed resources for infection prevention and control activities.</p> <p>EP 3 The organization provides equipment and supplies to support infection prevention and control activities.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.5.(b)(2)</p> <p>(2) Cleanroom garb must be donned and removed outside the designated area.</p>		<p>EC.02.01.01 The organization manages safety and security risks.</p> <p>EP 3 The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	

CCR Number §1751.5.(b)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.5.(b)(3)</p> <p>(3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.</p>	<p>EC.02.01.01 The organization manages safety and security risks.</p> <p>EP 3 The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.5.(b)(4)</p> <p>(4) Head and facial hair must be kept out of the critical area or be covered.</p>	<p>EC.02.01.01 The organization manages safety and security risks.</p> <p>EP 3 The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</p> <p>IC.01.02.01 Organization leaders allocate needed resources for infection prevention and control activities.</p> <p>EP 3 The organization provides equipment and supplies to support infection prevention and control activities.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.5.(b)(5)</p> <p>(5) Gloves made of low-shedding materials are required.</p>	<p>EC.02.01.01 The organization manages safety and security risks.</p> <p>EP 3 The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</p>		

CCR Number §1751.5.(b)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p data-bbox="932 115 2028 147">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="961 175 1999 224">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 245 2028 302">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 326 1999 448">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 469 1719 493">EP 2 The organization manages the implementation of policies and procedures.</p>	
<p data-bbox="44 521 170 545">§1751.5.(c)</p> <p data-bbox="44 578 898 630">(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.</p>			

CCR Number §1751.6.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.			
<p>§1751.6.</p> <p>§1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.</p>			
<p>§1751.6.(a)</p> <p>(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.</p>	<p>MM.06.01.03 Medications are safely and accurately administered by patients and families. Note: The term self-administered medication(s) may refer to medications administered by a family member.</p>		
<p>EP 1 If self-administration of medications is allowed by patients or families, written processes that address training, supervision, and documentation guide the safe and accurate self-administration of medications or the administration of medications by a family member. (See also MM.06.01.01, EPs 1 and 2)</p>			
<p>EP 2 The organization implements its written processes for medication self-administration or medication administration.</p>			
<p>EP 3 The organization educates patients and families involved in self-administration about the following: Medication name, type, and reason for use. (See also MM.06.01.01, EP 9; PC.02.03.01, EP 10)</p>			
<p>EP 4 The organization educates patients and families involved in self-administration about the following: How to administer medication, including process, time, frequency, route, and dose. (See also MM.06.01.01, EP 9; PC.02.03.01, EP 10)</p>			
<p>PC.02.03.01 The organization provides patient education and training based on each patient's needs and abilities.</p>			
<p>EP 10 Based on the patient's condition and assessed needs, the education and training provided to the patient by the organization include the following:</p> <ul style="list-style-type: none"> - An explanation of the plan for care, treatment, or services - Procedures to follow if care, treatment, or services are disrupted by a natural disaster or emergency - Basic health practices and safety - Information on the safe and effective use of medications. (See also MM.06.01.01, EP 9; MM.06.01.03, EPs 3-6) - Nutrition interventions (for example, supplements) and modified diets - Infection prevention and control - Discussion of pain, the risk for pain, the importance of effective pain management, the pain assessment process, and methods for pain management - Information on personal hygiene and grooming - Information on oral health - Basic physical and structural home safety - Information on the safe and effective use of medical equipment or supplies provided by the organization - Information on the storage, handling, and access to medical gases and supplies - Information on the identification, handling, and safe disposal of hazardous medications and infectious wastes - Habilitation or rehabilitation techniques to help the patient reach maximum independence - Information on the use of restraint 			

CCR Number §1751.6.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.6.(b)</p> <p>(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.</p>		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 14 Technical staff are competent to deliver and set up equipment, provide services, and train patients and caregivers.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	
<p>§1751.6.(c)</p> <p>(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.</p>		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	
<p>§1751.6.(d)</p> <p>(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.</p>		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	

CCR Number §1751.6.(e)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.6.(e)</p> <p>(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:</p>			
<p>§1751.6.(e)(1)</p> <p>(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:</p>			
<p>§1751.6.(e)(1)(A)</p>		<p>HR.01.05.03 Staff participate in ongoing education and training.</p>	
<p>(A) Aseptic technique.</p>		<p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>	
		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(A)			<p data-bbox="961 115 1717 139">EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.6.(e)(1)(B)	(B) Pharmaceutical calculations and terminology.	<p data-bbox="932 167 1673 191">HR.01.05.03 Staff participate in ongoing education and training.</p> <p data-bbox="961 224 1940 272">EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p data-bbox="932 297 1690 321">HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p data-bbox="961 354 1995 402">EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p data-bbox="961 427 1995 475">EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p data-bbox="961 500 1995 548">EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p data-bbox="961 638 1743 662">EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p data-bbox="961 686 2016 735">EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p data-bbox="961 760 1959 784">EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p data-bbox="932 808 1673 833">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="961 865 1995 914">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 938 1969 987">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 1011 1988 1060">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 1157 1717 1182">EP 2 The organization manages the implementation of policies and procedures.</p>	
§1751.6.(e)(1)(C)	(C) Sterile product compounding documentation.	<p data-bbox="932 1206 1673 1230">HR.01.05.03 Staff participate in ongoing education and training.</p> <p data-bbox="961 1263 1940 1312">EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p data-bbox="932 1336 1690 1360">HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p data-bbox="961 1393 1995 1442">EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(C)			<p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.6.(e)(1)(D)			<p>HR.01.05.03 Staff participate in ongoing education and training.</p>
(D) Quality assurance procedures.			<p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>
			<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(D)			<p data-bbox="953 115 1955 139">EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p data-bbox="932 164 1675 188">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="961 220 1990 269">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 293 1969 342">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 375 1990 423">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 513 1717 537">EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.6.(e)(1)(E)	(E) Aseptic preparation procedures.		<p data-bbox="932 565 1675 589">HR.01.05.03 Staff participate in ongoing education and training.</p> <p data-bbox="961 621 1940 670">EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>
			<p data-bbox="932 695 1688 719">HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p data-bbox="961 751 1990 800">EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p data-bbox="961 824 1990 873">EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p data-bbox="961 898 2011 1011">EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p data-bbox="961 1036 1745 1060">EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p data-bbox="961 1084 2011 1133">EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p data-bbox="953 1157 1955 1182">EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p data-bbox="932 1206 1675 1230">LD.04.01.01 The organization complies with law and regulation.</p> <p data-bbox="961 1263 1990 1312">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(E)		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.6.(e)(1)(F)	(F) Proper gowning and gloving technique.	HR.01.05.03	<p>Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>
		HR.01.06.01	<p>Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>
		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number §1751.6.(e)(1)(G)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.6.(e)(1)(G)</p> <p>(G) General conduct in he controlled area.</p>		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.6.(e)(1)(H)</p> <p>(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.</p>		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(H)			<p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p> <p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.6.(e)(1)(I)	(I) Sterilization techniques.		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p> <p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>

CCR Number §1751.6.(e)(1)(l)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
§1751.6.(e)(1)(J) (J) Container, equipment, and closure system selection.		<p>HR.01.05.03 Staff participate in ongoing education and training.</p> <p>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</p>	
		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p> <p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p> <p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.6.(e)(1)(J)			EP 2 The organization manages the implementation of policies and procedures.
§1751.6.(e)(2)		HR.01.04.01	The organization provides orientation to staff.
<p>(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.</p>	EP 3	The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.	
	EP 4	The organization orients staff on the following: Their specific job duties, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7; RI.01.01.01, EP 8)	
	HR.01.05.03	Staff participate in ongoing education and training.	
	EP 1	Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.	
	HR.01.06.01	Staff are competent to perform their responsibilities.	
	EP 1	The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.	
	EP 2	The organization uses assessment methods to determine the individual's competence in the skills being assessed.	
	EP 3	An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.	
	EP 5	Staff competence is initially assessed and documented as part of orientation.	
	EP 6	Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.	
	EP 16	The organization maintains copies of competency assessments for personnel who provide services.	
	LD.04.01.01	The organization complies with law and regulation.	
	EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
	EP 2	The organization manages the implementation of policies and procedures.	

CCR Number §1751.7.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Sterile Injectable Compounding Quality Assurance and Process Validation.			
§1751.7.			
§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.			
§1751.7.(a)	LD.04.01.01 The organization complies with law and regulation.		
(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:	EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.		
	LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.		
	EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.		
	EP 2 The organization manages the implementation of policies and procedures.		
	LD.04.04.01 Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)		
	EP 1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3) Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care.		
	EP 2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 14-15)		
	EP 3 Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.		
	EP 4 Performance improvement occurs organization-wide.		
	MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.		
	EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)		
	EP 2 The organization analyzes data on its medication management processes.		
	EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.		
	EP 4 The organization reviews the literature and other external sources for new technologies and best practices.		

CCR Number §1751.7(a)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p>
			<p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p>
			<p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p>
			<p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
			<p>PI.01.01.01 The organization collects data to monitor its performance.</p>
			<p>EP 1 The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)</p>
			<p>EP 2 The organization identifies the frequency for data collection.</p>
			<p>EP 3 The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)</p>
			<p>EP 21 The organization collects data on adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infection, and hospitalizations).</p>
			<p>PI.02.01.01 The organization compiles and analyzes data.</p>
			<p>EP 1 The organization compiles data in usable formats.</p>
			<p>EP 2 The organization identifies the frequency of data analysis.</p>
			<p>EP 4 The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.</p>
			<p>EP 5 The organization compares data with external sources, when available.</p>
			<p>EP 8 The organization uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5; PI.03.01.01, EP 1)</p>
			<p>PI.03.01.01 The organization improves performance.</p>
			<p>EP 1 Leaders prioritize the identified improvement opportunities. (See also PI.02.01.01, EP 8)</p>
			<p>EP 2 The organization takes action on improvement priorities.</p>
			<p>EP 3 The organization evaluates actions to confirm that they resulted in improvements. Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that improvement actions are evaluated for effectiveness.</p>
			<p>EP 4 The organization takes action when it does not achieve or sustain planned improvements.</p>

CCR Number §1751.7.(a)(1)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.7.(a)(1)</p> <p>(1) Cleaning and sanitization of the parenteral medication preparation area.</p>		<p>EQ.02.01.01 The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</p> <p>EP 4 The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.</p> <p>EP 5 The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.</p> <p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>	
<p>§1751.7.(a)(2)</p> <p>(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.</p>		<p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p> <p>EP 7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.</p> <p>EP 18 The organization periodically inspects all medication storage areas.</p> <p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p>	

CCR Number §1751.7.(a)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p> <p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
<p>§1751.7.(a)(3)</p> <p>(3) Actions to be taken in the event of a drug recall.</p>		<p>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</p>	<p>EP 1 The organization has a written policy describing how it will retrieve and handle medications within the organization that are recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration.</p> <p>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</p> <p>EP 3 When a medication is recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration, the organization notifies the prescribers and those who dispense or administer the medication.</p> <p>EP 4 When required by law and regulation or organization policy, the organization informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the U.S. Food and Drug Administration.</p>
<p>§1751.7.(a)(4)</p> <p>(4) Written justification of the chosen expiration dates for compounded sterile injectable products.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p>	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>
<p>§1751.7.(b)</p> <p>(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken,</p>		<p>HR.01.06.01 Staff are competent to perform their responsibilities.</p>	<p>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</p> <p>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</p> <p>EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.</p>

CCR Number §1751.7.(b)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
	and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.	<p>EP 5 Staff competence is initially assessed and documented as part of orientation.</p> <p>EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.</p> <p>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</p>	
		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.7.(c)		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p>
(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.		<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p>

CCR Number §1751.7.(c)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>
§1751.7.(d)			<p>LD.04.01.01 The organization complies with law and regulation.</p>
(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.			<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.07 The organization safely prepares medications.</p> <p>EP 1 When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.</p> <p>EP 2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</p> <p>EP 3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.06.01.01, EP 4)</p> <p>EP 4 The organization uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.</p> <p>MM.08.01.01 The organization evaluates the effectiveness of its medication management processes.</p> <p>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</p> <p>EP 2 The organization analyzes data on its medication management processes.</p> <p>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</p> <p>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</p> <p>EP 5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management processes.</p>

CCR Number §1751.7.(d)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
			<p>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</p> <hr/> <p>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</p> <hr/> <p>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.8.	Sterile Injectable Compounding Reference Materials.		
<p data-bbox="44 164 142 188">§1751.8.</p> <p data-bbox="44 224 701 248">§1751.8. Sterile Injectable Compounding Reference Materials.</p> <p data-bbox="44 277 894 358">In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.</p>	<p data-bbox="932 164 1990 220">LD.03.03.01 Leaders use organization-wide planning to establish structures and processes that focus on safety and quality.</p>		
		<p data-bbox="961 245 1986 269">EP 4 Leaders provide the resources needed to support the safety and quality of care, treatment, or services.</p>	
		<p data-bbox="932 293 1675 318">LD.04.01.01 The organization complies with law and regulation.</p>	
		<p data-bbox="961 349 1990 399">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p data-bbox="932 423 1969 474">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p>	
		<p data-bbox="961 505 1990 623">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards

CCR Number §1751.10.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Furnishing to Parenteral Patient at Home.			
§1751.10.	LD.04.01.01 The organization complies with law and regulation.		
<p>§1751.10. Furnishing to Parenteral Patient at Home.</p> <p>Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.</p>	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p>		
<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>			
<p>EP 2 The organization manages the implementation of policies and procedures.</p>			
<p>PC.02.01.03 The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.</p>			
<p>EP 1 Prior to providing care, the organization obtains or renews orders (verbal or written) from a licensed independent practitioner in accordance with professional standards of practice and law and regulation.</p>			
<p>EP 3 The organization consults with the prescribing physician as needed to confirm the physician's order(s).</p>			
<p>EP 4 The organization reviews orders and prescriptions for appropriateness and accuracy before providing care, treatment, or services.</p>			
<p>EP 5 Prior to implementing an order or prescription, staff obtain answers to any questions that exist. (See also MM.05.01.01, EP 11)</p>			

CCR Number §1751.11.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Furnishing to Home Health Agencies and Licensed Hospices.			
§1751.11.	LD.04.01.01	The organization complies with law and regulation.	
<p>§1751.11. Furnishing to Home Health Agencies and Licensed Hospices.</p> <p>Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.</p>	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>		
	<p>EP 2 The organization manages the implementation of policies and procedures.</p>		
	MM.05.01.11	The organization safely dispenses medications.	
	<p>EP 2 The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice. Note: Dispensing practices and recordkeeping include antidiversion strategies.</p>		
	MM.05.01.13	The organization safely obtains medications when the pharmacy is closed.	
	<p>EP 1 The organization has a process for providing medications to meet patient needs when the pharmacy is closed.</p>		
	<p>EP 7 The organization implements its process for providing medications to meet patient needs when the pharmacy is closed.</p>		
§1751.11.(a)	LD.04.01.01	The organization complies with law and regulation.	
<p>(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:</p>	<p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	<p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p>		
	<p>EP 2 The organization manages the implementation of policies and procedures.</p>		
	MM.01.01.03	The organization safely manages high-alert and hazardous medications.	
	<p>EP 3 The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)</p>		

CCR Number §1751.11.(a)(1)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.11.(a)(1)</p> <p>(1) furnished by a registered pharmacist;</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.11 The organization safely dispenses medications.</p> <p>EP 2 The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice. Note: Dispensing practices and recordkeeping include antidiversion strategies.</p>		
<p>§1751.11.(a)(2)</p> <p>(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.11 The organization safely dispenses medications.</p> <p>EP 2 The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice. Note: Dispensing practices and recordkeeping include antidiversion strategies.</p>		
<p>§1751.11.(a)(3)</p> <p>(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		

CCR Number §1751.11.(a)(3)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
<p>§1751.11.(a)(4)</p> <p>(4) labeled on the outside of the container with a list of the contents;</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	
		<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</p> <p>EP 1 Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> <p>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</p> <p>EP 3 All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</p> <p>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</p>	
<p>§1751.11.(a)(5)</p> <p>(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.</p>		<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>	

CCR Number §1751.11.(a)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p>		
<p>§1751.11.(b)</p> <p>(b) The portable container may contain up to:</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		
<p>§1751.11.(b)(1)</p> <p>(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>		
	<p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>		

CCR Number §1751.11.(b)(2)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(2) (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(3) (3) two vials of urokinase 5000 units;		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(4) (4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(A)		LD.04.01.01	The organization complies with law and regulation.
(A) heparin sodium lock flush 100 units/mL;	EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
EP 2	The organization manages the implementation of policies and procedures.		
§1751.11.(b)(4)(B)		LD.04.01.01	The organization complies with law and regulation.
(B) heparin sodium lock flush 10 units/mL;	EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
EP 2	The organization manages the implementation of policies and procedures.		
§1751.11.(b)(4)(C)		LD.04.01.01	The organization complies with law and regulation.
(C) epinephrine HCl solution 1:1000;	EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
	LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.	
	EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
EP 2	The organization manages the implementation of policies and procedures.		

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(D)			LD.04.01.01 The organization complies with law and regulation.
(D) epinephrine HCl solution 1:10,000;			<p data-bbox="963 175 1990 224">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 245 1969 293">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="963 326 1990 448">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="963 469 1717 493">EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(4)(E)			LD.04.01.01 The organization complies with law and regulation.
(E) diphenhydramine HCl 50mg/mL;			<p data-bbox="963 576 1990 625">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 646 1969 695">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="963 727 1990 849">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="963 870 1717 894">EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(4)(F)			LD.04.01.01 The organization complies with law and regulation.
(F) methylprednisolone 125mg/2mL;			<p data-bbox="963 977 1990 1026">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 1047 1969 1096">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="963 1128 1990 1250">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="963 1271 1717 1295">EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(G)		LD.04.01.01	The organization complies with law and regulation.
(G) normal saline, preserved, up to 30 mL vials;		EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
		LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.	
		EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
		EP 2 The organization manages the implementation of policies and procedures.	
§1751.11.(b)(4)(H)		LD.04.01.01	The organization complies with law and regulation.
(H) naloxone 1mg/mL 2 mL;		EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
		LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.	
		EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
		EP 2 The organization manages the implementation of policies and procedures.	
§1751.11.(b)(4)(I)		LD.04.01.01	The organization complies with law and regulation.
(I) droperidol 5mg/2mL;		EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.	
		LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.	
		EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.	
		EP 2 The organization manages the implementation of policies and procedures.	

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(J)		LD.04.01.01	The organization complies with law and regulation.
(J) prochlorperazine 10mg/2mL;		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.
§1751.11.(b)(4)(K)		LD.04.01.01	The organization complies with law and regulation.
(K) promethazine 25mg/mL;		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.
§1751.11.(b)(4)(L)		LD.04.01.01	The organization complies with law and regulation.
(L) dextrose 25gms/50mL;		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.

CCR Number §1751.11.(b)(4)(M)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(M) (M) glucagon 1mg/mL;		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(4)(N) (N) insulin (human) 100 units/mL;		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(b)(4)(O) (O) bumetamide 0.5mg/2mL;		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(4)(P)		LD.04.01.01	The organization complies with law and regulation.
(P) furosemide 10mg/mL;		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.
§1751.11.(b)(4)(Q)		LD.04.01.01	The organization complies with law and regulation.
(Q) EMLA Cream 5 gm tube;		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.
§1751.11.(b)(4)(R)		LD.04.01.01	The organization complies with law and regulation.
(R) Lidocaine 1 percent 30mL vials.		EP 2	The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.

CCR Number §1751.11.(b)(5)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(b)(5) (5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures.		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(c) (c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(c)(1) (1) implement and maintain policies and procedures for:		LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(c)(1)(A)	(A) the storage, temperature stability and transportation of the portable container;	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.03.01.01 The organization safely stores medications.</p> <p>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</p>
§1751.11.(c)(1)(B)	(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.06.01.01 The organization safely administers medications.</p> <p>EP 2 Only authorized licensed independent practitioners and clinical staff administer medications. Note: This does not prohibit self-administration of medications by patients, when indicated. (See also MM.06.01.03, EP 1)</p> <p>EP 3 Before administration, the individual administering the medication does the following: Verifies that the medication selected matches the medication order and product label. (See also MM.05.01.09, EP 1)</p>
§1751.11.(c)(1)(C)	(C) a specific treatment protocol for the administration of each medication contained in the portable container.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(c)(1)(C)		LD.04.01.07	<p>The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(c)(2)	(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(d)	(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>
§1751.11.(e)	(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p>

CCR Number §1751.11.(e)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
		LD.04.01.07	The organization has policies and procedures that guide and support patient care, treatment, or services.
		EP 1	Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.
		EP 2	The organization manages the implementation of policies and procedures.
		MM.04.01.01	Medication orders or prescriptions are clear and accurate.
		EP 11	For hospices that elect to use The Joint Commission deemed status option: Physicians give verbal medication orders only to a licensed nurse, nurse practitioner, pharmacist, or another physician.
		EP 13	The organization implements its written processes for medication orders or prescriptions.
		MM.05.01.01	A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.
		EP 1	For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.
		PC.02.01.03	The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.
		EP 1	Prior to providing care, the organization obtains or renews orders (verbal or written) from a licensed independent practitioner in accordance with professional standards of practice and law and regulation.
		EP 2	For home health agencies that elect to use The Joint Commission deemed status option: The organization obtains physician orders for therapy services, including the specific procedures, modalities, and the amount, frequency, and duration of their use.
		EP 3	The organization consults with the prescribing physician as needed to confirm the physician's order(s).
		EP 4	The organization reviews orders and prescriptions for appropriateness and accuracy before providing care, treatment, or services.
		EP 5	Prior to implementing an order or prescription, staff obtain answers to any questions that exist. (See also MM.05.01.01, EP 11)
		RC.02.03.07	Qualified staff receive and record verbal orders.
		EP 2	Only authorized staff receive and record verbal orders.
		EP 3	For home health agencies that elect to use The Joint Commission deemed status option: Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist responsible for furnishing or supervising the ordered care, treatment, or services.

CCR Number §1751.11.(f)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
<p>§1751.11.(f)</p> <p>(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p>	
	<p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>	<p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>	
<p>§1751.11.(g)</p> <p>(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>	<p>LD.04.01.01 The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>	

CCR Number §1751.11.(h)	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
§1751.11.(h)	(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>
§1751.11.(i)	(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.	LD.04.01.01	<p>The organization complies with law and regulation.</p> <p>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p>EP 2 The organization manages the implementation of policies and procedures.</p> <p>MM.05.01.19 The organization safely manages returned medications.</p> <p>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</p> <p>EP 2 When the organization accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy or organization that includes procedures for preventing diversion.</p> <p>EP 4 The organization implements its process for managing unused, expired, or returned medications.</p>

CCR Number §1751.12.	California Code of Regulations	Joint Commission Equivalent Number	Joint Commission Standards
Obligations of a Pharmacy Furnishing Portable Containers.			
§1751.12.	LD.04.01.01 The organization complies with law and regulation.		
§1751.12. Obligations of a Pharmacy Furnishing Portable Containers.	<p data-bbox="961 224 1990 269">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 293 1969 345">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 375 1990 496">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 516 1717 540">EP 2 The organization manages the implementation of policies and procedures.</p>		
§1751.12.(a)	LD.04.01.01 The organization complies with law and regulation.		
(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1751.11.	<p data-bbox="961 621 1990 667">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 691 1969 743">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 773 1990 894">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 914 1717 938">EP 2 The organization manages the implementation of policies and procedures.</p>		
§1751.12.(b)	LD.04.01.01 The organization complies with law and regulation.		
(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1751.11.	<p data-bbox="961 1021 1990 1066">EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</p> <p data-bbox="932 1091 1969 1143">LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</p> <p data-bbox="961 1172 1990 1294">EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. Note: For hospices that elect to use The Joint Commission deemed status option, establishment of policies governing the provision of hospice care is the responsibility of the hospice's interdisciplinary group.</p> <p data-bbox="961 1313 1717 1338">EP 2 The organization manages the implementation of policies and procedures.</p>		

Attachment 2

**Proposal to Add § 1727.2. to Article 3 of Division 17 of Title 16 of the
California Code of Regulations to read as follows:**

§ 1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 851 and 4207, Business and Professions Code.

**Proposal to Amend § 1728. in Article 3 of Division 17 of Title 16 of the
California Code of Regulations to read as follows:**

§ 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 144, 851 and 4200, Business and Professions Code.

Attachment 3

Proposal to Amend § 1728. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 01/11) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as~~ a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

(4) A sealed original Self Query from the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is/has been submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and 4202~~, 4207, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and 4202~~, 4207, 4402, and 4400 Business and Professions Code; Section 11105 of the Penal Code; and Sections 1706.2. and 1793.6. of Title 16 of the California Code of Regulations.



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STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

APPLICATION FOR A PHARMACY TECHNICIAN LICENSE

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets of paper if necessary.

Applicant Information - Please Type or Print

Full Legal Name-Last Name	First Name	Middle Name
Previous Names (AKA, Maiden Name, Alias, etc)		
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc)		
City	State	Zip Code
Residence Address (if different from above)		
City	State	Zip Code
Home#	Cell#	Work#
Email Address		
Date of Birth (Month/Day/Year)	**Social Security No	Driver's License #
		State

Mandatory Education (check one box)

Section 4202(a) of the Business and Professions Code requires an applicant for a pharmacy technician license to be a **high school graduate or possess a general education development (GED) equivalent.** Please check the appropriate box below certifying that you have meet this requirement in order to apply for a pharmacy technician license.

High school graduate Date graduated: _____

Completed General Education Development (GED) Date GED awarded: _____

TAPE A COLOR PASSPORT STYLE
 PHOTOGRAPH (2"X2") TAKEN
 WITHIN
 60 DAYS OF THE FILING OF THIS
 APPLICATION

**NO POLAROID
 OR
 SCANNED IMAGES**

PHOTO MUST BE ON PHOTO
 QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(1)(2)(3)(4) of the Business and Professions Code.

Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

Attached is a certified copy of PTCB certificate - Date certified: _____

Attached is a certified copy of your military training DD214

Self-Query Report by the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)

Attached is the sealed envelope containing my Self-Query Report from the NPDB-HIPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

Photo	<input type="checkbox"/>	FP Cards/Live Scan	<input type="checkbox"/>	License no	App fee no
Enf 1 st Check	<input type="checkbox"/>	FP Cards Sent	<input type="checkbox"/>	_____	_____
Enf 2 nd Check	<input type="checkbox"/>	FP Fees	<input type="checkbox"/>	Date issued	Amount
Qualify Code	_____	DOJ Clear Date:	_____	_____	_____
HIPDB	<input type="checkbox"/>	FBI Clear Date:	_____	Date expires	Date cashiered
				_____	_____

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

<p>1. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? If "yes," attach a statement of explanation. If "no," proceed to #2. Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? If "yes," attach a statement of explanation.</p> <p style="margin-left: 20px;"><u>If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.</u></p>	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>2. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?</p> <p style="margin-left: 20px;"><u>If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances?</u> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach a statement of explanation.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>3. Has disciplinary action ever been taken against your pharmacist license, intern permit or technician license in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>4. Have you ever had an application for a pharmacist license, intern permit or technician license denied in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>5. Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state? If "yes," provide the name of company, type of permit, type of action, year of action and state.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>6. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>7. Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?</p> <p style="margin-left: 20px;"><u>Check the box next to "YES" if, you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.</u></p> <p style="margin-left: 20px;"><u>Check the box next to "NO" if you have not been convicted of a crime.</u></p> <p style="margin-left: 20px;"><u>You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</u></p> <p>Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)

APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code Sections 4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by Civil Code Section 1798.40.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Records Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code Section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

** Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect purposes.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state, and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as is practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars (\$1,000), or by both that imprisonment and fine.

For further details about these requirements, consult Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and subsequent sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____, hereby attest to the fact that I am the applicant whose signature
(Print Full Legal Name)

appears below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I have read the instructions attached to this application.

Signature of Applicant

Date



California State Board of Pharmacy
 1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
 www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

**AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION
 FOR PHARMACY TECHNICIAN**

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on ____/____/____.
(completion date must be included)

Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on ____/____/____.
(graduation date must be included)

Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on ____/____/____.
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: ____/____/____

Affix school seal here.

OR

Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here.

University, College,
or School of
Pharmacy Name: _____

Address: _____

Print Name of
Director, Registrar,
or Pharmacist: _____

Phone
Number: _____

Email: _____

Attachment 4

July 10, 2009

Virginia Herold
Executive Director
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Petition to the Board of Pharmacy to Waive Certain Requirements

Dear Ms. Herold:

PETNET Solutions, Inc. (PETNET) doing business in California as PETNET Pharmaceutical, operates 44 radiopharmacies (nuclear pharmacies) in the US which specialize solely in the compounding and dispensing of patient specific unit doses of radiopharmaceuticals utilized in Positron Emission Tomography (PET) scanning. PETNET operates four radiopharmacies in the state of California. Under the provisions of the California Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4118, *Waiving of Minimum Requirements by Board*, PETNET is submitting this letter as petition to the California Board of Pharmacy requesting that the Board grant waivers to PETNET to the following California codes:

- Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a), which states, in part, "No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
- California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d), and (e), which addresses:
 - Possession of a key to the pharmacy restricted to a pharmacist
 - The requirement of an applicant for a pharmacy license to certify that the applicant meets the requirements of the section.

Background:

Pharmacies that compound PET radiopharmaceuticals differ from the conventional radiopharmacies in that a nuclear pharmacist in a conventional radiopharmacy compounds and dispenses radiopharmaceutical doses upon a physician's prescription order, and which doses are prepared from commercially available cold kits, radio-nuclide generators, and ready-to-dispense finished radiopharmaceutical drug products. PETNET, on the other hand, compounds and dispenses only radiopharmaceuticals intended for use in Positron Emission Tomography Imaging (PET). The activity of compounding PET radiopharmaceuticals entails the use of highly sophisticated particle accelerators (cyclotrons) and automated chemical synthesis apparatus. Complex testing equipment is also necessary to perform quality control testing. Conventional pharmacies and traditional radiopharmacies do not require such types of highly sophisticated production and testing equipment.

Because the equipment required to compound and test PET radiopharmaceuticals is sophisticated and complex, they need to be maintained, serviced and repaired continually by trained cyclotron engineers who are experts with such equipment. These engineers are listed on the Radioactive Materials License for the pharmacy as Cyclotron Operators, (CO), a category of Authorized Users in California as defined by the California Department of Public Health,

Radiological Health Branch. This incurs on the CO legal permission to operate and to maintain the cyclotron and other related equipment, and to handle radioactive materials.

Generally, PETNET radiopharmacies are open for business from around 10PM to 4PM the following day, during which time the PET radiopharmaceutical drugs are compounded, quality control tested, and dispensed to the prescribing physician's practice upon prescription orders, all of which occurs under the direct supervision of a licensed pharmacist, who is also an authorized nuclear pharmacist. The compounding and dispensing operation, occurring when the pharmacy is open for business during the times mentioned above, provides for an 18 hour per day, six days a week operation.

By necessity, the service, maintenance and repair performed by the CO takes place during non-business hours (generally between the hours of 4PM and 10PM), which allows time for the radiation field in and around the production equipment to decrease after the last compounding operation which occurs by late morning or early afternoon. This allows the COs to perform their job in a safer environment by nature of the decreased radiation fields. It is necessary and essential that any repair and maintenance activities by the CO occur during the hours that the pharmacy is not operational (i.e. no compounding, dispensing, or order-taking activities are occurring).

In some of our nuclear pharmacy facilities, the cyclotron is accessible only through the permitted pharmacy space; in all the pharmacies the automated chemical synthesis equipment (compounding equipment) is located in the pharmacy space.

To be compliant with the current codes, it is necessary for PETNET to retain a pharmacist during the hours that the pharmacy is not operational (i.e., not compounding, dispensing, or taking orders), whether it involves paying regular pharmacist staff overtime, or bringing in a contract pharmacist to babysit the CO. We use the term "babysit" since the pharmacists (PETNET staff or contract) do not have the knowledge, technical skills, or credentials required by the California Department of Public Health, Radiological Health Branch, to actually provide any kind of meaningful assistance or supervision to the maintenance and repair activities of the CO. The time a pharmacist is required to be at the pharmacy during the necessary presence of the CO, is generally non-productive and the pharmacist is usually on overtime. Many times a pharmacist is not available to be at the facility during non-operational periods. As a result, necessary service, maintenance and repairs usually performed by the CO is delayed or postponed. This has created a situation where the dependability of our operations has suffered. As a result, the reliability of the supply of these important diagnostic radiopharmaceuticals to California citizens is placed in jeopardy.

Also, because of the extra demanding hours placed on our pharmacist staff, and the lack of any meaningful responsibility during the times that service is being performed on equipment, our ability to attract and retain qualified nuclear pharmacists, a scarce human resource, has also been compromised.

Petition Waiver Request:

By way of this letter, PETNET is petitioning the Board to grant certain waivers to the code to cover the following California pharmacies:

- PETNET Solutions, Inc, Palo Alto, license # PHY 48657
- PETNET Solutions, Inc., Sacramento, license # PHY 48660
- PETNET Solutions, Inc., Irvine, license # PHY 48659
- PETNET Solutions, Inc., Culver City, license # PHY 48658

We are requesting the following waivers:

- Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a)
 - **Waiver Request:** Allow personnel listed as Cyclotron Operator/Engineer on the Radioactive Material License access to the permitted space (pharmacy area) during non-operational hours without the presence of a pharmacist for the sole purpose of maintenance and repair of the cyclotron, automated synthesis equipment, and quality control testing equipment.

- California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d) and (f)
 - **Waiver Request 1714(d):** Allow the CO access to the permitted pharmacy space by issuing cipher lock combination numbers to the CO. A conventional key will not be issued.
 - **Waiver Request 1714(f):** Allow an applicant for a licensed premise or for a renewal of that license to certify that it meets the requirements of Section 1714 and to attach a copy of the waiver to said application, should the Board grant a waiver, or comply with other actions as determined by the Board.

Why waivers will not impact patient safety or standards of care:

PETNET believes that the granting of the requested waivers will not compromise the high standard of patient safety, consistent with good patient care for the following reasons:

1. Radiopharmaceuticals are not subject to abuse, diversion, or counterfeiting. The California Board of Pharmacy recently added credence to this statement by exempting radiopharmaceuticals from the requirements of the e-Pedigree rules, as codified in Section 4034 of the Business and Professions Code. There is virtually no cause, benefit, or any potential motivation for a non-pharmacist employee to cause diversion of these products, or to abuse the products.
2. Because of the specific radioactive nature of Positron Emitting radiopharmaceuticals, by virtue of the type of radioactive decay and the very short physical half-life of the isotope, there is no potential for theft or diversion for terrorist purposes.
3. At the time that the CO would be left unsupervised by a pharmacist, most of the PET radiopharmaceuticals compounded that day are already dispensed, or the radioactivity in the remainder of each vial has decayed down to unusable amounts.
4. PETNET does not stock any conventional diagnostic or therapeutic radiopharmaceuticals such as cold kits or generators, or other therapeutic interventional pharmaceuticals such as those that may be stocked and dispensed by traditional nuclear pharmacies.
5. The only other "dangerous drugs" that are found (stocked, but not for sale) in a PETNET pharmacy are sterile water for injection, and sodium chloride for injection. These are used in the compounding of the PET radiopharmaceutical. Similarly, these drugs are not subject to diversion or abuse.
6. Legend devices such as sterile IV extension sets, sterile stopcocks, sterile empty vials, and similar devices which are necessary for compounding are stocked in the pharmacy. Such types of devices are not known to be subject to diversion or abuse.
7. Sterile disposable syringes and needles are stocked. These devices are used for dispensing of patient doses in addition to their function as implements in the compounding process. These devices, at times, may be required for use by the CO during the repair and testing of the synthesis or QC testing equipment. A limited supply of syringes and needles will be made available to the CO for this purpose. The bulk stock of these devices will be stored in a manner to render them inaccessible after the pharmacy is closed for business.
8. PETNET does not possess a DEA license and does not possess, stock or sell any controlled substances.

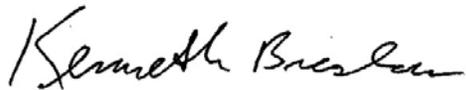
9. PETNET radiopharmacies are not visible to the public nor does the general public have access to these premises.
10. The premises are secured 24/7 by way of all external entrances being locked by default.

Additional controls that PETNET will exercise are:

1. Access to patient prescription records and the pharmacy computer systems is restricted to PETNET pharmacists only.
2. All PETNET personnel that work in a pharmacy have undergone mandatory HIPPA training.

Thank you in advance of the Boards consideration of this waiver request. If you have any questions please feel free to call me at 865-218-2383

Sincerely,



Kenneth Breslow, R.Ph. MS
Senior Regulatory Affairs Specialist
PETNET Solutions, A Siemens Company
865-218-2383
Kenneth.Breslow@siemens.com

CC:
Doug Derry
Anthony Stagnolia
Michael Nazerias
Josh Nutting
Dwayne Mar

Business and Professions Code

4116. Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

(b) (1) The board may, by regulation, establish reasonable security measures consistent with this section in order to prevent unauthorized persons from gaining access to the area, place, or premises or to the controlled substances or dangerous drugs or dangerous devices therein.

(2) The board shall, by regulation, establish conditions for the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing authorized personnel from the pharmacy. These conditions shall ensure the security of the pharmacy and its operations during the temporary absence of the pharmacist and shall allow, at the discretion of the pharmacist, nonpharmacist personnel to remain and perform any lawful activities during the pharmacist's temporary absence.

Title 16 California Code of Regulations

1714. Operational Standards and Security.

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy 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. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

Authority cited: Sections 4005 and 4116, Business and Professions Code. Reference: Sections 4116 and 4117, Business and Professions Code.

Attachment 5

**California State Board of Pharmacy
CPJE Statistics 4/1/10 – 9/30/10**

The charts below display data for all candidates who took the CPJE examination between 4/1/10 – 9/30/10, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

Overall Pass Rates

CPJE

		Frequency	Percent
Valid	F	235	17.7
	P	1095	82.3
	Total	1330	100.0

NAPLEX

		Frequency	Percent
Valid	F	61	4.7
	P	1227	95.3
	Total	1288	100.0

Location of School

CPJE

			JPE		JPE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	62	679	741	17	718	735
		% within school	8.4	91.6	100.0	2.3	97.7	100.0
	Other US	Count	112	333	445	18	396	414
		% within school	25.2	74.8	100.0	4.3	95.7	100.0
	Foreign	Count	61	77	138	26	107	133
		% within school	44.2	55.8	100.0	19.5	80.5	100.0
	Unclassified	Count	0	6	6	0	6	6
		% within school	0	100.0	100.0	0	100.0	100.0
Total		Count	235	1095	1330	61	1227	1288
		% within school	17.7	82.3	100.0	4.7	95.3	100.0

Gender

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	146	764	910	38	845	883
		% within gender	16.0	84.0	100.0	4.3	95.7	100.0
	M	Count	89	331	420	23	382	405
		% within gender	21.2	78.8	100.0	5.7	94.3	100.0
Total		Count	235	1095	1330	61	1227	1288
		% within gender	17.7	82.3	100.0	4.7	95.3	100.0

Degree

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree	BS Pharm	Count	67	94	161	30	124	154
		% within degree	41.6	58.4	100.0	19.5	80.5	100.0
	Pharm D.	Count	168	1001	1169	31	1103	1134
		% within degree	14.4	85.6	100.0	2.7	97.3	100.0
Total		Count	235	1095	1330	61	1227	1288
		% within degree	17.7	82.3	100.0	4.7	95.3	100.0

California Schools

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	8	100	108	0	107	107
		% within school	7.4	92.6	100.0	0	100.0	100.0
	UOP	Count	19	167	186	5	180	185
		% within school	10.2	89.8	100.0	2.7	97.3	100.0
	USC	Count	8	156	164	2	162	164
		% within school	4.9	95.1	100.0	1.2	98.8	100.0
	Western	Count	11	104	115	6	108	114
		% within school	9.6	90.4	100.0	5.3	94.7	100.0
	Loma Linda	Count	7	45	52	2	49	51
		% within school	13.5	86.5	100.0	3.9	96.1	100.0
	UCSD	Count	6	41	47	0	46	46
		% within school	12.8	87.2	100.0	0	100.0	100.0
	Touro U	Count	3	66	69	2	66	68
		% within school	4.3	95.7	100.0	2.9	97.1	100.0
Total		Count	62	679	741	17	718	735
		% within school	8.4	91.6	100.0	2.3	97.7	100.0

US Schools of Pharmacy

	JPE pass fail status		Total
	F	P	
Auburn	0	3	3
U of AZ	1	6	7
U of AR	0	3	3
UCSF	8	100	108
U of Pacific	19	167	186
USC	8	156	164
U of CO	1	5	6
U of Conn	1	5	6
Howard DC	0	2	2
FL A&M	2	2	4
U of FL	3	9	12
Mercer	0	1	1
U of GA	0	3	3
Idaho SU	1	2	3
U of IL Chi	4	11	15
Butler U	1	2	3
Purdue	1	9	10
Drake	2	4	6
U of IA	0	3	3
U of KS	0	2	2
U of KY	0	2	2
NE LA U	1	1	2
Xavier	3	2	5
U of MD	4	5	9
MA Col Pharm	10	18	28
NE-MA	1	9	10
Ferris	0	1	1
U of MI	1	4	5
Wayne SU	0	2	2
U of MN	2	5	7
St. Louis Col of PH	0	2	2
UMKC	0	3	3
U of MT	1	3	4
Creighton	1	7	8
U of NE	0	4	4
Rutgers	0	2	2

	JPE pass fail status		Total
	F	P	
U of NM	0	4	4
Western	11	104	115
Midwestern U	2	14	16
Chicago			
A&M Schwartz	1	5	6
St. Johns	2	2	4
SUNY-Buff	2	3	5
Union U	0	1	1
UNC	2	5	7
ND SU	0	1	1
OH Nrthrn U	1	3	4
OH State U	2	6	8
U of Cinn	2	3	5
U of Toledo	1	1	2
SW OK State	1	2	3
U of OK	0	3	3
OR State U	1	6	7
Duquesne	0	2	2
Phi C of Pharm	1	2	3
Temple	4	7	11
U of Pitt	0	1	1
U of RI	3	1	4
U of SC	1	1	2
TX SO U	1	1	2
U of Hous	1	2	3
U of TX	1	4	5
U of UT	2	1	3
Med C of VA	1	1	2
U of WA	2	13	15
WA State U	0	5	5
U of WI-Mad	0	6	6
U of WY	0	1	1
Campbell U	1	0	1
Nova Southeastern	6	9	15
Wilkes University	1	0	1
Bernard J Dunn	2	2	4

	JPE pass fail status		Total
	F	P	
Midwestern AZ	6	8	14
Nevada College of Pharm	7	38	45
Loma Linda U	7	45	52
UCSD	6	41	47
MA School of Pharm - Worcester	1	3	4
Palm Beach Atlantic University	1	5	6
Lake Erie Col	0	5	5
Touro U	3	66	69
U of Charleston	3	2	5

	JPE pass fail status		Total
	F	P	
U of Appalachia	2	4	6
South U School of Pharm	0	1	1
Hampton U (VA)	1	0	1
Pac U of Or	6	6	12
Wingate U	0	1	1
Unclassified	0	6	6
Other/FG	61	77	138
	235	1095	1330

Country

	JPE pass fail status		Total
	F	P	
Armenia	0	1	1
Bulgaria	1	1	2
Brazil	0	1	1
Canada	0	1	1
Switzerland	1	0	1
China	0	1	1
E&W Germany	0	1	1
Egypt	8	11	19
United Kingdom	1	2	3
Israel/West Bank/Gaza Strip	0	1	1
India	16	18	34
Iraq	0	1	1
Iran	2	2	4
Italy	1	1	2
Japan	1	0	1
Jordan	2	1	3
S. Korea	2	4	6
Lebanon	0	4	4
Nigeria/New Guinea	1	1	2
Philippines	16	16	32
Romania	0	1	1
Sweden	0	1	1
Serbia	1	0	1
USSR	0	1	1
Syria	0	1	1
Turkmenistan	0	1	1
Taiwan	2	0	2
Ukraine	1	0	1
USA	178	1020	1198
Uzbekistan	1	0	1
Yugoslavia	0	1	1
South Africa	0	1	1
Total	235	1095	1330

Attachment 6

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	137	102	132										371
Pharmacist (initial licensing applications)	203	343	169										715
Intern pharmacist	50	472	381										903
Pharmacy technician	776	955	870										2601
Pharmacy	19	28	28										75
Pharmacy - Temp	0	5	10										15
Sterile Compounding	5	4	4										13
Sterile Compounding - Temp	0	0	0										0
Clinics	4	2	8										14
Hospitals	6	0	0										6
Hospitals - Temp	0	0	0										0
Nonresident Pharmacy	4	8	5										17
Nonresident Pharmacy - Temp	0	0	0										0
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	2	2	3										7
Nonresident Wholesalers	10	11	9										30
Nonresident Wholesalers - Temp	0	0	2										2
Wholesalers	7	9	6										22
Wholesalers - Temp	0	1	0										1
Veterinary Food-Animal Drug Retailer	0	0	0										0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0										0
Designated Representatives	36	42	39										117
Total	1259	1984	1666	0	0	0	0	0	0	0	0	0	4909

*u/a denotes unavailable

** denotes corrected

*** denotes change in method of collecting date effective 03/2010

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Issued													
Pharmacist	179	471	77										727
Intern pharmacist	72	310	544										926
Pharmacy technician	752	932	794										2478
Pharmacy	21	18	23										62
Pharmacy - Temp	0	0	0										0
Sterile Compounding	3	1	1										5
Sterile Compounding - Temp	0	0	0										0
Clinics	9	6	3										18
Hospitals	1	2	0										3
Hospitals - Temp	0	0	0										0
Nonresident Pharmacy	4	0	10										14
Nonresident Pharmacy - Temp	0	0	0										0
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	2	0	2										4
Nonresident Wholesalers	4	3	4										11
Nonresident Wholesalers - Temp	0	0	0										0
Wholesalers	4	6	6										16
Wholesalers - Temp	0	0	0										0
Veterinary Food-Animal Drug Retailer	0	0	0										0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0										0
Designated Representatives	16	29	41										86
Total	1067	1778	1505	0	4350								
Pending													
Pharmacist Examination	725	566	622										622
Pharmacist Examination Eligible	1043	1043	979										979
Intern pharmacist	270	441	274										274
Pharmacy technician	2505	2550	2697										2697
Pharmacy	75	81	85										85
Sterile Compounding	24	26	26										26
Clinics	29	26	23										23
Hospitals	8	8	6										6
Nonresident Pharmacy	43	51	40										40
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	12	15	12										12
Nonresident Wholesalers	78	86	74										74
Wholesalers	48	49	47										47
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	188	197	180										180
Total	5048	5139	5065	0	5065								

r/u/a denotes unavailable

** denotes corrected

*** denotes change in method of collecting date effective 03/2010

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Change of Pharmacist-in-Charge***													
Received	104	128	102										334
Processed	118	132	99										349
Pending	389	385	388										388
Change of Exemptee-in-Charge***													
Received	8	9	6										23
Processed	4	0	7										11
Pending	108	117	116										116
Change of Permits													
Received	48	69	54										171
Processed	4	44	15										63
Pending	222	247	286										286
Discontinuance of Business***													
Received	20	21	10										51
Processed	0	0	28										28
Pending	135	156	138										138
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1572	1339											2911
Pharmacy technician	2958	2262											5220
Pharmacy	407	298											705
Sterile Compounding	26	17											43
Clinics	106	68											174
Nonresident Pharmacy	31	20											51
Licensed Correctional Facility	0	0											0
Hypodermic Needle and Syringes	17	10											27
Nonresident Wholesalers	56	43											99
Wholesalers	73	27											100
Veterinary Food-Animal Drug Retailer	2	1											3
Designated Representative	155	113											268
Total	5403	4198	0	9601									

*u/a denotes unavailable

** denotes corrected

*** denotes change in method of collecting date effective 03/2010

Attachment 7



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES**

DATE: October 5, 2010

LOCATION: First Floor Hearing Room
Department of Consumer Affairs
Sacramento, CA 95834

BOARD MEMBERS PRESENT:

Greg Lippe, Chair
Kenneth Schell, PharmD
Deborah Veale, PharmD

BOARD MEMBERS ABSENT:

Ryan Brooks

STAFF PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Carolyn Klein, Legislation and Regulations Manager
Kristy Schieldge, DCA Staff Counsel

Call to Order

Chair Lippe called the meeting to order at 1:35 p.m.

1. Review of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

At the April Board Meeting board staff were directed to (1) review and assess the three accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding

pharmacies, (2) bring staff's report to a future Licensing Committee Meeting, and (3) bring the committee's recommendations to the board for action at a future meeting.

The committee was advised that Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was the only accreditation agency in attendance at the meeting.

Supervising Inspector Janice Dang provided background of the criteria used to evaluate the accreditation agencies as well as the findings of the random unannounced inspections completed by the board. Dr. Dang provided background information on JCAHO and how that organization performs its accreditation. Janice provided her findings on review of JCAHO's process as it relates to the board's criteria. She provided specific information on JCAHO's performance and expectations detailed in the board's criteria.

Mark Crafton, representing JCAHO provided an overview of their accreditation process and indicated that typically a survey can be conducted in 4-6 weeks of the opening on a new facility, but it depends on the nature of the change. If the services are being provided by a current accredited facility "original hospital," then the next inspection would be completed as part of the next regular triennial survey. JCAHO indicated that it depends of the services that are going to be provided at the new site and provided examples of when a new survey would not be required based upon their rules

Executive Officer Herold framed the issue for the committee members and provided background. Ms. Herold stated that JCAHO is already in the statute and as such evaluation of this agency is not necessarily required under existing law. Ms. Herold discussed the disparity between how our board regulates sterile injectable compounding pharmacy and sought clarification on how a new satellite pharmacy under common ownership with a pharmacy already accredited by JCAHO. Specifically Ms. Herold asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided are similar to the already accredited hospital without doing an inspection. Mr. Crafton answered yes.

JCAHO indicated that they now perform a periodic performance review – similar to the board's self-assessment program. The results of this review are required to be filed with JCAHO. He also indicated that JCAHO completes a 5% random surveys annually as well as completes "for cause" survey where they believe the quality and safety is compromised.

Ms. Herold inquired if the committee feels that a pharmacist should participate in the JCAHO survey. The committee discussed the issue and spoke in support of this requirement.

Public Comment

Dr. Gray, representing Kaiser Permanente, stated that the committee may want to discuss how this requirement would be implemented if the hospital has a drug room in lieu of a pharmacy as well as seek clarification from JCAHO if it extends accreditation to a hospital licensed by California Department of Public Health.

Motion: Request that JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.

M/S: Schell/Veale

Support: 2 Oppose: 0 Abstain: 1

2. Proposed Regulations to Modify Application Requirements for Intern Pharmacists, Pharmacy Technicians and Pharmacists to Require “Self-Query” Reports From the Healthcare Integrity and Protection Data Bank (HIPDB)

Chair Lippe stated that at the July Board Meeting, the board approved two proposals to (1.) require pharmacists and pharmacist interns and (2.) require pharmacy technicians to provide a “self query” report from the National Practitioners Data Bank-- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as a condition of application for licensure in California. The process for pharmacy technicians will be discussed under the next agenda item.

The committee was advised that it is not unusual for a pharmacist applicant or intern to also be licensed in other jurisdictions. As part of the application process for both the intern and pharmacist exam applications, applicants are required to self-disclose several items. The intern application includes several questions surrounding whether prior disciplinary action has ever been taken in this state or any other. The pharmacist exam application includes several of the same types of questions as well as information about licensure in other states. This information is all self-certified by the applicant. In addition, the board requires license verification from any state where a pharmacist applicant is also licensed.

Public Comment

Dr. Gray sought clarification on which exams this would apply to. Staff clarified that because the regulation references section 4200 of the Business and Professions Code, it would apply for the application for the CPJE and NAPLEX exam

Motion: Authorize the Executive Officer to initiate the rulemaking processes to adopt the language that has been proposed. (language below)

Amend Section 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

- (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
- (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
- (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
- (4) A signed copy of the examination security acknowledgment.
- (5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.
- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Add section 1727.2 to 16 CCR:

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

M/S: Schell/Veale

Support: 3 Oppose: 0 Abstain: 0

3. Proposal to Initiate a Regulation Change To Update the Pharmacy Technician Application

Chair Lippe provided an overview of the issue. At the July Board Meeting, the board directed staff to make modifications to the pharmacy technician application that will reduce the number of deficiencies in submitted applications and to add a requirement that a “self query” report from the National Practitioners Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) be added as an application requirement.

Further, at the July Board Meeting, the board was advised that about 50 percent of the technician applications submitted to the board have one or more deficiencies. This slows the processing of the application and delays licensure for qualified applicants. Staff believes that the proposed modifications will help reduce processing time for applicants and ensure that those technicians disciplined by other states are known to the board before California issues a pharmacy technician application.

The committee requested clarification from board staff on the nature of the deficiencies and solutions being offered. Staff Manager Debi Mitchell highlighted some of the changes that are being incorporated into the revised form. She indicated that some of the changes being offered are to ensure consistent use of language between statute and regulation, e.g. “license” vs. “registration.”

Ms. Herold also highlighted to committee members that the processing time on the application information will reflect a 60 day processing time.

The committee discussed the use of “registration” versus “license” and directed staff to ensure that all references should use the term “license.”

Public Comment

Dr. Gray advised the committee that use of the term “licensee” has implications that the term “registration” does not. Specifically, in Division 2, a licensee is responsible for reporting requirements for elder and child abuse.

Motion: Authorize the executive officer take all steps necessary to initiate the rulemaking to update the application form and HIPDB self-query report as presented. (language below)

Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 01/11)) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as a pharmacy technician~~ license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

(4) A sealed original Self-Query from the National Practitioner Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is/has been submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within ~~30-60~~ days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and 4202, 4207, 4402, and 4400~~ Business and Professions Code, Section 11105 of the Penal Code, and sections 1706.2. and 1793.6. of Title 16 of the California Code of Regulations.

M/S: Veale/Schell

Support: 3 Oppose: 0 Abstain: 0

(The application being incorporated by reference in this regulation is attached, following this meeting summary.)

4. Request from PETNET Solutions for a Waiver of Security Requirements for Pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present.

Josh Nutting, Pharm.D, representing PETNET Solutions provided background to the committee on the basis for their request. Specifically, PETNET was seeking a waiver of Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a) to allow personnel listed as Cyclotron Operator/Engineer on the Radioactive Material License access to the permitted space (pharmacy area) during non-operational hours without the presence of a pharmacist for the sole purpose of maintenance and repair of the cyclotron, automated synthesis equipment, and quality control testing equipment.

PETNET was also seeking a waiver to California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d) and (f) to allow the CO (Cyclotron Operator/Engineer) access to the permitted pharmacy space by issuing cipher lock combination numbers to the CO and to allow an applicant for a licensed premises or for a renewal of that license to certify that it meets the requirements of Section 1714 and to attach a copy of the waiver to the application, should the board grant a waiver, or comply with other actions as determined by the board.

Dr. Nutting stated that the longer the company waits to conduct the maintenance following a work day, the lower the radiation fields. Business operations need to run 24 hours a day and, since the pharmacy closes at 4 p.m., no pharmacy operations that occur from 4 p.m. to 10 p.m. Under current regulation, PetNet is required to have a pharmacist come in a sit for 4 hours in order to meet regulation requirements.

The committee sought clarification on the safeguards in place and was advised that some equipment could be locked up when the pharmacy was closed.

The committee was advised that the board does not have the authority to waive a statutory requirement. Ms. Herold offered that a possible solution would be a legislative change. Ms. Herold suggested that a narrowly drafted statutory change to Business and Professions Code section 4116, may allow PETNET to obtain the authorization it seeks. Ms. Herold indicated that should section 4116 be amended, the board could then consider the waiver request to California Code of Regulations Section 1714.

There was no additional committee discussion and no public comment.

5. Discussion about a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas.

Chair Lippe provided background on this issue. Specifically, the committee was advised that at several prior meetings of the board or its committees, including the last meeting of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Pharmacists are required to earn 30 hours of approved continuing education credit every two years as a condition of renewal. Requirements for continuing education in both statute and regulation follow this page. Pharmacy technicians are not required to earn CE to maintain board licensure, although to be certified by the Pharmacy Technician Certification Board (a method to qualify for initial registration), they have a CE requirement

The committee discussed previous content required continue education as well as the requirements in other states that specify course content. Dr. Veale suggested that patient consultation may be one area to consider, especially given the board's efforts in improving patient safety.

Dr. Schell spoke in support of the concept. Dr. Schell indicated that coursework in ethics may be of value and that the board sees too many inventory issues that result in discipline and that this may also be appropriate.

Dr. Veale indicated that the committee needs to determine what the goal of the specific CE requirement – to respond to enforcement related issues or is it patient care issues.

Public Comment:

Steve Gray, representing Kaiser, and Lynn Rolston, representing CPhA, provided public comment. Dr. Gray indicated that there are chronic problems e.g. inventory diversion and prevention, as well as issues surrounding changes in law, e.g., quality assurance programs. Dr. Gray suggested that subject matter identified by the board to fill in gaps in education that can be evaluated periodically. He suggested that substance abuse, inventory management and disaster response could be ongoing. However issues such as compounding regulations, would not require ongoing CE, but perhaps on a short term to ensure pharmacists are educated on the changes in the law. Dr. Gray stated that the board may need to also specify that only live CE accredited by the board be acceptable.

Lynn Rolston indicated that continuing education offerings have changed and expanded the type of coursework that the board accepts, that it almost requires that certain topics need to be required by the board to ensure quality. She also spoke in support on in-person courses for specified courses. She spoke in support of the board requiring CE when a significant law changes e.g., compounding regulations.

Chair Lippe concluded that this issue requires further discussion and requested that the time be brought back to a future committee meeting.

There was no additional committee discussion or public comment.

6. Department of Consumer Affairs' Request that Health Care Boards Evaluate the Federal Healthcare Reform Act's Impact on Present and Future Licensees and their Licensing Acts

Ms. Herold indicated that in March, the Federal Health Care Reform Act was enacted federally and advised the committee that since that time, the director has asked that the board examine how it will affect how health care is delivered in California, particularly to prepare for larger number of patients.

Ms. Herold advised that committee that a presentation will be given to the board during the October Board Meeting to provide information on pharmacy-related issues.

There was no additional committee discussion and no public comment.

7. Competency Committee Report

Chair Lippe advised the committee that a quality assurance review of the CPJE was initiated on August 2, 2010. Mr. Lippe indicated that this process is done periodically to ensure the reliability of the CPJE examination. As of the date of this report, the quality assurance review has been completed and results have been released.

The committee was also advised that both Competency Committee workgroups met in August 2010 at the annual meeting to discuss examination development. Each Competency Committee workgroup will also meet once in the fall of 2010 for examination development. Each workgroup will ensure the new outline will be used to develop examinations administered after April 1, 2011.

There was no additional committee discussion and no public comment.

8. Licensing Statistics

The committee reviewed the licensing statistical report provided with the meeting materials.

Dr. Veale requested clarification on the number of pending exam applications and was advised that staff will better define what is included in the numbers presented in the report.

There was no additional committee discussion and no public comment.

9. Public Comments for Items Not on the Agenda

Eric Mahone requested clarification on the identification requirements established by the board for exam administration purposes. He suggested that the board consider the risk vs. benefit to a middle name not matching on the two required forms of identification required.

Staff counsel advised the committee that there could not be discussion on this item as it was not agendaized, but encouraged Mr. Mahone to speak with the board's Executive Officer at the conclusion of the meeting.

There was no additional public comment.

The meeting was adjourned at 3:45 p.m.



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STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

APPLICATION FOR A PHARMACY TECHNICIAN LICENSE

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets of paper if necessary.

Applicant Information - Please Type or Print

Full Legal Name-Last Name	First Name	Middle Name
Previous Names (AKA, Maiden Name, Alias, etc)		
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc)		
City	State	Zip Code
Residence Address (if different from above)		
City	State	Zip Code
Home#	Cell#	Work#
Email Address		
Date of Birth (Month/Day/Year)	**Social Security No	Driver's License #
		State

Mandatory Education (check one box)

Section 4202(a) of the Business and Professions Code requires an applicant for a pharmacy technician license to be a **high school graduate or possess a general education development (GED) equivalent.** Please check the appropriate box below certifying that you have meet this requirement in order to apply for a pharmacy technician license.

High school graduate Date graduated: _____

Completed General Education Development (GED) Date GED awarded: _____

TAPE A COLOR PASSPORT STYLE
 PHOTOGRAPH (2"X2") TAKEN
 WITHIN
 60 DAYS OF THE FILING OF THIS
 APPLICATION

**NO POLAROID
 OR
 SCANNED IMAGES**

PHOTO MUST BE ON PHOTO
 QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(1)(2)(3)(4) of the Business and Professions Code.

Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

Attached is a certified copy of PTCB certificate - Date certified: _____

Attached is a certified copy of your military training DD214

Self-Query Report by the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)

Attached is the sealed envelope containing my Self-Query Report from the NPDB-HIPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

Photo	<input type="checkbox"/>	FP Cards/Live Scan	<input type="checkbox"/>	License no	App fee no
Enf 1 st Check	<input type="checkbox"/>	FP Cards Sent	<input type="checkbox"/>	_____	_____
Enf 2 nd Check	<input type="checkbox"/>	FP Fees	<input type="checkbox"/>	Date issued	Amount
Qualify Code	_____	DOJ Clear Date:	_____	_____	_____
HIPDB	<input type="checkbox"/>	FBI Clear Date:	_____	Date expires	Date cashiered
				_____	_____

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

<p>1. <u>Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? If "yes," attach a statement of explanation. If "no," proceed to #2.</u> <u>Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program?</u> If "yes," attach a statement of explanation.</p> <p style="margin-top: 20px;"><u>If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.</u></p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>2. <u>Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?</u></p> <p><u>If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances?</u> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach a statement of explanation.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>3. <u>Has disciplinary action ever been taken against your pharmacist license, intern permit or technician license in this state or any other state?</u> If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>4. <u>Have you ever had an application for a pharmacist license, intern permit or technician license denied in this state or any other state?</u> If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>5. <u>Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state? If "yes," provide the name of company, type of permit, type of action, year of action and state.</u></p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>6. <u>Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.</u></p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<p>7. <u>Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?</u></p> <p><u>Check the box next to "YES" if, you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.</u></p> <p><u>Check the box next to "NO" if you have not been convicted of a crime.</u></p> <p><u>You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</u></p> <p>Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 15%;">Arrest Date</th> <th style="width: 15%;">Conviction Date</th> <th style="width: 30%;">Violation(s)</th> <th style="width: 40%;">Court of Jurisdiction (Full Name and Address)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>		Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)																
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APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code Sections 4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by Civil Code Section 1798.40.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Records Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code Section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

** Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect purposes.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state, and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as is practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars (\$1,000), or by both that imprisonment and fine.

For further details about these requirements, consult Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and subsequent sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____, hereby attest to the fact that I am the applicant whose signature
_____ (Print Full Legal Name)

appears below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I have read the instructions attached to this application.

Signature of Applicant

Date



California State Board of Pharmacy
 1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
 www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

**AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION
 FOR PHARMACY TECHNICIAN**

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on ____/____/____.
(completion date must be included)

Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on ____/____/____.
(graduation date must be included)

Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on ____/____/____.
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: ____/____/____

Affix school seal here.

OR

Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here.

University, College,
 or School of
 Pharmacy Name: _____

Address: _____

Print Name of
 Director, Registrar,
 or Pharmacist: _____

Phone
 Number: _____

Email: _____

Attachment 8

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within three work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
		# of Apps. Received:				Average Days to Process:			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	371				35			
	Pharmacist (initial licensing)	715				4			
	Pharmacy Intern	903				9			
	Pharmacy Technician	2,601				28			
	Pharmacies	81				16			
	Non-Resident Pharmacy	17				28			
	Wholesaler	22				25			
	Veterinary Drug Retailers	0				0			
	Designated Representative	117				24			
	Out-of-state distributors	30				24			
	Clinics	14				16			
	Hypodermic Needle & Syringe Distributors	7				13			
	Sterile Compounding	13				12			
	Change of Permit	171				45			
Pharmacist in Charge	334				19				
Designated Representative in Charge	23				45				
Discontinuance of Business	51				66				

2. Process 100 percent of all deficiency documents within five work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	5			
Pharmacist (initial licensing)	7			
Pharmacy Intern	7			
Pharmacy Technician	14			
Pharmacies	8			
Non-Resident Pharmacy	4			
Wholesaler	4			
Veterinary Drug Retailers	4			
Designated Representative	4			
Out-of-state distributors	4			
Clinics	8			
Hypodermic Needle & Syringe	4			

3. Make a licensing decision within three work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	2			
Pharmacist (initial licensing)	2			
Pharmacy Intern	2			
Pharmacy Technician	3			
Pharmacies	3			
Non-Resident Pharmacy	5			
Wholesaler	5			
Veterinary Drug Retailers	0			
Designated Representative	2			
Out-of-state distributors	5			
Clinics	3			
Hypodermic Needle & Syringe	2			

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	272			
Pharmacy Intern	926			
Pharmacy Technician	2,478			
Pharmacies	65			
Non-Resident Pharmacy	14			
Wholesaler	16			
Veterinary Drug Retailers	0			
Designated Representative	86			
Out-of-state distributors	11			
Clinics	18			
Hypodermic Needle & Syringe	4			
Sterile Compounding	5			

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	81			
Pharmacies	2			
Non-Resident Pharmacy	5			
Clinics	3			
Sterile Compounding	0			
Designated Representative	12			
Hypodermic Needle & Syringe	3			
Out-of-state distributors	19			
Wholesaler	5			
Veterinary Drug Retailers	0			
Registered Pharmacist	155			
Intern Pharmacist	1			

6. Deny applications to those who do not meet California standards.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	2			
Intern Pharmacist	0			
Pharmacy Technician	21			
Pharmacies	0			
Non-Resident Pharmacy	1			
Clinics	0			
Sterile Compounding	0			
Designated Representative	0			
Hypodermic Needle & Syringe	0			
Out-of-state distributors	0			
Wholesaler	0			

7. Responding to e-mail status requests and inquiries to designated e-mail addresses.

	Qtr 1 *	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	645			
Pharmacy Technicians	498			
Site licenses (pharmacy, clinics)	1,284			
Site licenses (wholesalers, nonresident pharmacies)	925			
Pharmacist in Charge	219			
Renewals	269			

8. Responding to telephone status request and inquiries.

	Qtr 1 *	Qtr 2 **	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	82			
Pharmacy Technicians	*			
Site licenses (pharmacy, clinics)	369			
Site licenses (wholesalers, nonresident pharmacies)	221			
Pharmacist in Charge	49			
Renewals	1,138			

* 2nd Qtr - Voicemail status requests for pharmacy technicians has been suspended since 10/15/09 to allow board staff time to focus on processing applications and issuing licenses.

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.								
Measure:	Percentage of revenue cashiered application within 2 working days.								
Tasks:	Revenue Received:				Average Days to Process:				
	Qtr 1*	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
	Applications	\$435,845				3			
	Renewals	\$1,536,500				3			
	Cite and Fine	\$191,990				4			
	Probation/ Cost Recovery	\$24,214				4			
	Request for Information/ License Verification	\$3,175				3			
Fingerprint Fee	\$11,730				3				
* 1st quarter reflects July and August 2010 data available at the time of report development.									

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.																																																					
Measure:	Percentage of licensing records changes within five working days.																																																					
Tasks:	<table border="1" data-bbox="370 289 1523 571"> <thead> <tr> <th data-bbox="370 289 743 331"></th> <th colspan="4" data-bbox="743 289 1143 331">Requests Received:</th> <th colspan="4" data-bbox="1143 289 1523 331">Average Days to Process:</th> </tr> <tr> <th data-bbox="370 331 743 369"></th> <th data-bbox="743 331 857 369">Qtr 1</th> <th data-bbox="857 331 954 369">Qtr 2</th> <th data-bbox="954 331 1052 369">Qtr 3</th> <th data-bbox="1052 331 1143 369">Qtr 4</th> <th data-bbox="1143 331 1240 369">Qtr 1</th> <th data-bbox="1240 331 1338 369">Qtr 2</th> <th data-bbox="1338 331 1435 369">Qtr 3</th> <th data-bbox="1435 331 1523 369">Qtr 4</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 369 743 411">Address/Name Changes</td> <td data-bbox="743 369 857 411">3,120</td> <td data-bbox="857 369 954 411"></td> <td data-bbox="954 369 1052 411"></td> <td data-bbox="1052 369 1143 411"></td> <td data-bbox="1143 369 1240 411">5</td> <td data-bbox="1240 369 1338 411"></td> <td data-bbox="1338 369 1435 411"></td> <td data-bbox="1435 369 1523 411"></td> </tr> <tr> <td data-bbox="370 411 743 491">Off-site Storage Applications (approved)</td> <td data-bbox="743 411 857 491">24</td> <td data-bbox="857 411 954 491"></td> <td data-bbox="954 411 1052 491"></td> <td data-bbox="1052 411 1143 491"></td> <td data-bbox="1143 411 1240 491">20</td> <td data-bbox="1240 411 1338 491"></td> <td data-bbox="1338 411 1435 491"></td> <td data-bbox="1435 411 1523 491"></td> </tr> <tr> <td data-bbox="370 491 743 571">Transfer of Intern Hours to Other States</td> <td data-bbox="743 491 857 571">34</td> <td data-bbox="857 491 954 571"></td> <td data-bbox="954 491 1052 571"></td> <td data-bbox="1052 491 1143 571"></td> <td data-bbox="1143 491 1240 571">30</td> <td data-bbox="1240 491 1338 571"></td> <td data-bbox="1338 491 1435 571"></td> <td data-bbox="1435 491 1523 571"></td> </tr> </tbody> </table>										Requests Received:				Average Days to Process:					Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Address/Name Changes	3,120				5				Off-site Storage Applications (approved)	24				20				Transfer of Intern Hours to Other States	34				30			
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Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1490 287">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores. <li data-bbox="370 516 1490 657">2. Evaluate the drug distribution system of clinics and their appropriate licensure. <i>1st Qtr 09/10:</i> Continued to advise clinics and their advocates about the barrier the Capen decision places on surgicenters/clinics from obtaining a board clinic permit. A legislative solution is needed. <i>3rd Qtr 09/10:</i> Board hears presentation by Fort Sutter Surgery Center discussing the issue. <li data-bbox="370 701 1490 951">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure. <li data-bbox="370 961 1490 1287">4. Work with local and state officials on emergency preparedness and planning for pandemics and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>2nd Qtr 09/10:</i> Board votes that in declared emergencies where a board meeting cannot quickly be scheduled, a subcommittee of three members can make decisions for patient safety under provisions of Business and Professions Code section 4062 and the board's emergency response policy. <i>4th Qtr 09/10:</i> Licensing continued reviewing requests from CDPH seeking clarification on board disaster response policy. <li data-bbox="370 1297 1430 1325">5. Evaluate the need to issue a provisional license to pharmacy technician trainees.

6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.

Sep. 2006: *Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.*

Dec. 2006: *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*

March 2007: *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*

May 2007: *Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.*

Sep. 2007: *Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.*

Oct. 2007: *Board postpones work on this topic until CSHP and CPhA complete their review.*

March 2009: *Board executive staff meet with the executive director of the ExCPT exam.*

April 2009: *Board directs staff to secure a psychometric review of both the PTCB and ExCPT exams, in wake of AB 418 being stalled in the legislature.*

2nd Qtr 09/10: *Board initiates discussions with DCA regarding use of their Ph.D to evaluate the validation studies.*

7. Review requirements for qualifications of pharmacy technicians with stakeholders

4th Qtr 07/08: *Future work on the training of technicians will occur as joint activities of the pharmacist associations.*

Legislation to require an exam and continuing education for pharmacy technicians is dropped (AB 1947)

Board participates in CSHP sponsored stake holder meeting.

2nd Qtr 08/09: *Executive officer participates in a meeting with CPhA and CSHP to provide technical advice on proposed legislation to be introduced next year. Attend CSHP sponsored stakeholder meeting.*

3rd Qtr 08/09: *Senate Bill 418 introduced to add new requirements for technicians. SB 418 is later dropped for the year.*

8. **Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.**
Note: I-Licensing system has been cancelled and the BreEZe system will take its place.
July 2006: Board executive officer becomes executive sponsor of program.
Nov. 2006: Board completes system identification of parameters for each licensing program.
Dec. 2006 - Jan. 2007: Preparatory work and pilots completed; board staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.
3rd Qtr 08/09: Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward. ATS project implemented.
2nd Qtr 09/10: Board advised of new initiative to facilitate online applicant submission and renewal.
4th Qtr 09/10: Board analyst temporarily assigned to assist on BreEZe project.
9. **Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.**
3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).
Oct. 2007: Board considers basic internship competencies developed under the program and develops letter of support.
Oct. 2008: California Pharmacy Council meets to discuss Intern requirements.
Dec. 2009: Licensing Committee again discusses the requirements given that other states are no longer transferring intern hours.
10. **Implement new test administration requirements for the CPJE.**
March 2007: Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.
June 2007: Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.
4th Qtr 09/10: Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
2nd Qtr 07/08: Transition efforts to PSI continue.
3rd Qtr 07/08: New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.
1st Qtr 09/10: Competency Committee develops occupational analysis survey.
2nd Qtr 09/10: Competency Committee develops new content online for CPJE.
3rd Qtr 09/10: Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
11. **Participate in ACPE reviews of California Schools of Pharmacy.**
Oct. 2007: Board participates in review of California Northstate College of Pharmacy.
Jan. 2008: Board participates in review of UCSF.
March 2008: Board participates in review of Touro.
3rd Qtr 08/09: Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.
3rd Qtr 09/10: Board participates in ACPE review of the school of pharmacy at UOP.

- 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training.**
Sept. 2007: Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.
Oct. 2007: Board evaluates options for training of designated representatives.
Sept. 2008: Licensing Committee hears testimony regarding program.
June 2009: Evaluation of designated representative training scheduled for September.
- 13. Convene Committee to evaluate drug distribution within hospitals.**
2nd Qtr 08/09: Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.
3rd Qtr 08/09: Board establishes subcommittee to initiate review.
March 2009: First meeting convened.
June 2009: Second meeting convened in San Francisco.
Sept. 2009: Third meeting convened in Sacramento.
Dec. 2009: Work of Hospital Subcommittee nearly completed. Board to review parameters for recalls at January 2010 meeting.
2nd Qtr 09/10: Document finalized.
- 14. Improve reporting of and accounting for intern hours.**
4th Qtr 08/09: Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.
- 15. Participate in initiatives to increase the number of pharmacists in California to meet demand.**
4th Qtr 08/09: Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.
- 16. Assess the operations of specialty pharmacy services.**
4th Qtr 08/09: Board initiates review of refill pharmacies.
- 17. Encourage use of technology where it benefits the public.**
June 2009: Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.
Oct. 2009: Automation equipment demonstrated to Board that would facilitate unit dose packaging in hospitals and allow for barcoding.
Jan. 2010: Demonstration to Board if patient medication instructions in various languages accessible by emerging software available to pharmacies.
- 18. Secure the implementation of e-prescribing in California by the earliest possible date.**
4th Qtr 08/09: Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.
- 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.**
4th Qtr 08/09: Board assists the California Department of Public Health in responding to distribution of Tamiflu and Relenza. Pharmacy law requirements regarding labeling and dispensing not waived as standard and necessary pharmacists care could still be provided.
2nd Qtr 09/10: Board continues to work with Department of Public Health on H1N1 distribution issues.

- 20. Automate fingerprint background results with the Department of Justice.**
2nd Qtr 09/10: Began working with the DCA to implement automation of background results for applicants to be automatically imported into the board's Applicant Tracking System (ATS).
3rd Qtr 09/10: Continued working with the DCA on developing programming specifics in order to go live on February 17, 2010.
Board staff develops the procedures.
4th Qtr 09/10: Final revision to the procedures, trained staff, and assigned job task to staff.
Board staff continues to manage automated process and resolve issues.
- 21. Evaluate pharmacy technician, pharmacist, and intern pharmacist application process to identify areas for improvement and to modify the application requirements to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB).**
3rd Qtr 09/10: Staff reached out to pharmacy technician programs to advise them of statutory changes to the application fee.
Staff revised pharmacy technician application after reviewing most common deficiencies for legal review.
4th Qtr 09/10: Staff reached out to pharmacy technician programs educating them on the most common application deficiencies.
1st Qtr 10/11: Staff finalized the draft pharmacy technician, pharmacist, and intern pharmacist application.
Legal approved the draft pharmacy technician and intern pharmacist application.
2nd Qtr 10/11: Legal approved the pharmacist application.
Proposal to initial a regulation change to update the pharmacy technician application at the Licensing Committee meeting.
Licensing Committee made recommendations for board to pursue the changes to the pharmacy technician application.
Licensing Committee made recommendations for board to pursue the changes to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB) for the pharmacy technician, pharmacist, and intern pharmacist application for licensure.
- 22. Implement Fingerprint Requirement for Pharmacist Renewal.**
4th Qtr 09/10: Regulation approved by Office of Administrative Law (effective date of regulation is December 7, 2010).
Department drafted programming changes to accommodate requirement.
Board staff tested changes in a testing environment.
- 23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership.**
4th Qtr 09/10: Board staff developed standards for common ownership requirements.