<table>
<thead>
<tr>
<th>Criteria</th>
<th>Accreditation Commission for Health Care Inc. (ACHC)</th>
<th>Community Health Accreditation Program (CHAP)</th>
<th>Det Norske Veritas (DNV)</th>
<th>The Joint Commission (JCAHO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Periodic Inspections</td>
<td>Accreditation is valid for 3 years, requiring a full site inspection.</td>
<td>Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.</td>
<td>Triennial inspection for accreditation with annual ISO periodic inspections.</td>
<td>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.</td>
</tr>
<tr>
<td>2. Comparison of standards</td>
<td>Copy of pharmacy standards submitted.</td>
<td>Copy of pharmacy standards submitted.</td>
<td>Comparison table of standards to regulations was submitted.</td>
<td>Refer to crosswalk comparison submitted.</td>
</tr>
<tr>
<td>3. Surveyor’s qualifications.</td>
<td>• Maintain a current pharmacist license in one of the 50 states or territories of the U.S.</td>
<td>• 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.</td>
<td>• 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.</td>
<td>• In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience.</td>
</tr>
<tr>
<td></td>
<td>• Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred.</td>
<td>• Only a pharmacist would be assigned to survey a pharmacy.</td>
<td>• Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training.</td>
<td>• Pharmacist must have a Doctor of Pharmacy degree or equivalent.</td>
</tr>
<tr>
<td></td>
<td>• Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey.</td>
<td>• 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.</td>
<td>• All surveyors are evaluated in terms of their interpersonal skills.</td>
<td>• Nurses must have graduated from an approved school of nursing and have a Master’s degree in an appropriate discipline.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Job description provided.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• 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.

• Must complete 45 hours of continuing education in their discipline within every 3 year period.
• Must participate in annual surveyor training

• 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.
<p>| 4. Acceptance by major California payors | 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. | • 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 MediCare) | Medi-Caid and Medi-Care (CMS) approval 9/26/2008. | Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California. |
| 5. Subjected to Unannounced inspections by BOP | ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board. | • CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability. | • Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved. | Pharmacies subjected to the compounding regulations are accredited under The Joint Commission’s Comprehensive Accreditation Manual for Home Care – Pharmacy standards. List of accredited pharmacies was provided. |
| 6. Access to accreditor’s reports on individual pharmacies. | • 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. | • 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. | Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required. | 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>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 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. | •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. | •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. | •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>
<thead>
<tr>
<th>Criteria</th>
<th>Accreditation Commission for Health Care Inc. (ACHC)</th>
<th>Community Health Accreditation Program (CHAP)</th>
<th>Det Norske Veritas (DNV)</th>
<th>The Joint Commission (JCAHO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record keeping (CCR 1751.1, 1735.2, 1735.3)</td>
<td>Pharmacy #1 • Reviewed.</td>
<td>Pharmacy #1 • Add to compounding sheet equipment used. • Unable to retrieve electronic data for temperature monitoring.</td>
<td>Pharmacy #1 • Reviewed.</td>
<td>Pharmacy #1 • Supplies invoices not on premise for 3 years. • Add to compounding sheet equipment used.</td>
</tr>
<tr>
<td>Pharmacy #2 • Reviewed. • Document cleaning of TPN Compounder. • No c/s DEA inventory.</td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Labeling (CCR 1751.2, 1735.4)</td>
<td>Pharmacy #1 • New labeling implemented identifying products that are compounded.</td>
<td>Pharmacy #1 • Add statement the drug was compounded by pharmacy. • Label needs to contain generic name of drug.</td>
<td>Pharmacy #1 • Label on container missing name of prescriber. • Add statement the drug was compounded by pharmacy.</td>
<td>Pharmacy #1 • Add statement the drug was compounded by pharmacy.</td>
</tr>
<tr>
<td>Pharmacy #2 • Add Chemo – Dispose properly label. • Add statement the drug was compounded by the pharmacy.</td>
<td>Pharmacy #2 • Add statement the drug was compounded by pharmacy</td>
<td></td>
<td>Pharmacy #2 • Add generic name to label. • Add statement the drug was compounded by pharmacy.</td>
<td></td>
</tr>
<tr>
<td>Policy and procedures (CCR 1751.3, 1735.5)</td>
<td>Pharmacy #1 • Need p/p for QA program regarding potency, strength, integrity and quality.</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Pharmacy #2 • Add Chemo p/p. • Revise p/p to weekly cleaning of surfaces, walls, ceiling, workbench.</td>
<td>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.</td>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
ceiling, workbench surfaces.  • Need p/p for QA program regarding integrity, potency, quality and strength.

<table>
<thead>
<tr>
<th>Facility equipment (CCR 1751.4)</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Reviewed.</td>
<td>• Refrigerator/Freezer requiring defrosting.</td>
<td>• Reviewed.</td>
<td>• Temperature logs unavailable</td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Expired frozen drugs need to be quarantined and properly disposed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Card board boxes in cleanroom.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 4 refrigerators with only 1 being monitored; no thermometers. All containing drugs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reviewed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attire (CCR 1751.5)</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Need to order chemo spill kit and chemo gown/gloves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Reviewed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Reviewed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training staff, patient, caregiver (CCR 1751.6)</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Competency testing due.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Annual Competency testing overdue.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Reviewed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Add testing of terminology.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Annual restesting of competency overdue.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality assurance and process validation (CCR 1751.7)</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
<th>Pharmacy #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy #1</td>
<td>• Does end product testing for sterility, pyrogen testing only.</td>
<td>• Only sterility testing and end product testing conducted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Conduct QA testing on products mailed, temperature of drug when sent to cold and hot places.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>Pharmacy #2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td></td>
<td>• Not documenting corrective actions when QA testing on personnel performance, equipment and facility fails.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference materials (CCR 1751.8)</td>
<td>Pharmacy #1</td>
<td>Pharmacy #1 • Reviewed.</td>
<td>Pharmacy #1 • Reviewed.</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td>Pharmacy #2</td>
<td>Pharmacy #2 • Reviewed.</td>
<td>Pharmacy #2 • Reviewed.</td>
<td>Pharmacy #2 • Reviewed.</td>
<td></td>
</tr>
</tbody>
</table>
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.
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.
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?

www.jointcommission.org

Headquarters
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
630 792 5000 Voice
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
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.


**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735. Compounding in Licensed Pharmacies.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735.(a)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(a) &quot;Compounding&quot; means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:</td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC.02.01.03 The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization reviews orders and prescriptions for appropriateness and accuracy before providing care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>§1735.(a)(1)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(1) Altering the dosage form or delivery system of a drug</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1735.(a)(2)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(2) Altering the strength of a drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1735.(a)(2)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>§1735.(a)(3)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Combining components or active ingredients</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1735.(a)(4)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Preparing a drug product from chemicals or bulk drug substances</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1735.(b)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(b) &quot;Compounding&quot; 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.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735.(c)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(c) &quot;Compounding&quot; 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.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735.(d)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(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.).</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------</td>
<td>------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1735.(d)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
</tbody>
</table>

EP 2 The organization manages the implementation of policies and procedures.
### Compounding Definitions

#### §1735.1

The organization complies with law and regulation.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### §1735.1.(a)

(a) "Integrity" means retention of potency until the expiration date noted on the label.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### §1735.1.(b)

(b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### §1735.1.(c)

(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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### §1735.1.(d)

(d) "Strength" means amount of active ingredient per unit of a compounded drug product.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LD.04.01.01</th>
<th>The organization complies with law and regulation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>MM.05.01.09</td>
<td>Medications are labeled.</td>
</tr>
<tr>
<td>Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td></td>
</tr>
<tr>
<td>EP 4</td>
<td>All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</td>
</tr>
</tbody>
</table>
§1735.2. Compounding Limitations and Requirements.

(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.

(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.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(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

(2) is intended to avoid waste and loss of compounded drug product.
### §1735.2.(c)(2)

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(c)(2)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MM.05.01.11 The organization safely dispenses medications.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### §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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(c)(3)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### §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:

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(d)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### §1735.2.(d)(1)

(1) Active ingredients to be used.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(d)(1)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1735.2.(d)(2)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td>(2) Inactive ingredients to be used.</td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1735.2.(d)(3)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td>(3) Process and/or procedure used to prepare the drug.</td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.07</td>
<td>The organization safely prepares medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>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.</td>
</tr>
<tr>
<td>§1735.2.(d)(4)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td>(4) Quality reviews required at each step in preparation of the drug.</td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------</td>
<td>-----------------------------------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>
| §1735.2.(d)(4) |                             | 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. |
| §1735.2.(d)(5) |                             | 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.(d)(6) | Lahore compounding process or procedures required, if any. | 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.05.01.07 | Lahore safely prepares medications. | MM.05.01.07 The organization safely prepares 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) |
| §1735.2.(d)(6) | Lahore expiration dating 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. |
| | | 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.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. |
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(d)(6)</td>
<td></td>
<td>EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</td>
<td></td>
</tr>
<tr>
<td>§1735.2.(e)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735.2.(f)</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1735.2.(f)</td>
<td></td>
<td>HR.01.06.01 Staff are competent to perform their responsibilities.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### §1735.2.(f)

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(f)</td>
<td>Medications are labeled.</td>
<td>MM.05.01.09</td>
<td>Medications are labeled.</td>
</tr>
<tr>
<td></td>
<td>Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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.

- **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.

### §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.

### §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.

### §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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(i)</td>
<td>Joint Commission Equivalent Number</td>
</tr>
<tr>
<td></td>
<td>HR.01.06.01 Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 1</strong> The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 3</strong> 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.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 5</strong> Staff competence is initially assessed and documented as part of orientation.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 6</strong> 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.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 14</strong> Technical staff are competent to deliver and set up equipment, provide services, and train patients and caregivers.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 15</strong> The organization takes action when a staff member’s competence does not meet expectations.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 16</strong> The organization maintains copies of competency assessments for personnel who provide services.</td>
</tr>
<tr>
<td></td>
<td><strong>MM.03.01.01</strong> The organization safely stores medications.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 1</strong> The organization stores only approved medications and medications selected by the organization. (See also MM.02.01.01, EP 4)</td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 3</strong> The organization stores controlled (scheduled) medications to prevent diversion, in accordance with law and regulation.</td>
</tr>
<tr>
<td></td>
<td><strong>MM.05.01.07</strong> The organization safely prepares medications.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 1</strong> When an on-site licensed pharmacy is available, a pharmacist, or pharmacy staff under the supervision of a pharmacist, compunds 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.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</td>
</tr>
<tr>
<td></td>
<td><strong>EP 3</strong> 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)</td>
</tr>
<tr>
<td></td>
<td><strong>EP 4</strong> 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.</td>
</tr>
</tbody>
</table>
### §1735.2.(i) California Code of Regulations

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(i)</td>
<td>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td><strong>EP 1</strong> Medication containers are labeled whenever medications are prepared but not immediately administered. (See also MM.06.01.01, EP 3) <strong>Note 1:</strong> This element of performance does not apply to segregated pill boxes that store medications by day and time of day. <strong>Note 2:</strong> 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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 3</strong> All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 4</strong> All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 5</strong> All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 6</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 7</strong> When preparing individualized medications for multiple patients, the label also includes the following: The patient's name.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 8</strong> When preparing individualized medications for multiple patients, the label also includes the following: Directions for use and applicable accessory and cautionary instructions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 9</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 10</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 11</strong> The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 12</strong> Staff competence is assessed and documented once every three years, or more frequently as required by organization policy and in accordance with law and regulation.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### §1735.2.(j) California Code of Regulations

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.2.(j)</td>
<td>HR.01.06.01 Staff are competent to perform their responsibilities.</td>
<td><strong>EP 2</strong> The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 3</strong> An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. <strong>Note:</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 5</strong> Staff competence is initially assessed and documented as part of orientation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 6</strong> Staff competence is assessed and documented once every three years, or more frequently as required by organization policy and in accordance with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1735.2(j)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
</tbody>
</table>

is to promote compliance through self-examination and education.

EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
### Records of Compounded Drug Products.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**§1735.3.**

§1735.3. Records of Compounded Drug Products.

**§1735.3.(a)**

(a) For each compounded drug product, the pharmacy records shall include:

1. The master formula record.
2. The date the drug product was compounded.
3. The identity of the pharmacy personnel who compounded the drug product.

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.3.(a)(3)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

| §1735.3.(a)(4) |                               | 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. |

| §1735.3.(a)(5) |                               | 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. |

<p>| §1735.3.(a)(6) |                               | 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. |</p>
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.3.(a)(6)</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td>§1735.3.(a)(7)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1735.3.(a)(8)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1735.3.(a)(9)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1735.3.(a)(9)</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>§1735.3.(a)(10)</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1735.3.(b)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>
**MM.01.01.03** The organization safely manages high-alert and hazardous medications.

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.

EP 2 The organization has a process for managing high-alert and hazardous medications. (See also MM.03.01.01, EP 9)

EP 3 The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)

**MM.02.01.01** The organization selects and procures medications.

EP 2 The organization develops and approves criteria for selecting medications, which include the following:
- 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

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.

EP 6 The organization standardizes and limits the number of drug concentrations.

EP 7 The organization has a process to select and procure medications that are not on its list of medications.

EP 8 The organization implements the process to select and procure medications that are not on its medication list.

EP 9 Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.

**MM.03.01.01** The organization safely stores medications.

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 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.

(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.

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.3.(c)</td>
<td></td>
<td>MM.02.01.01 The organization selects and procures medications.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization develops and approves criteria for selecting medications, which include the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Indications for use (See also MM.05.01.01, EP 10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Effectiveness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Drug interactions</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Potential for errors and abuse</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Adverse drug events</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Sentinel event advisories</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Other risks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Costs</td>
<td></td>
</tr>
<tr>
<td>§1735.3.(d)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>

(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.
### §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).

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.4.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.05.01.09** Medications are labeled.

**Note:** This standard is applicable to all organizations that prepare and administer medications.

**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.

**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 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.

#### §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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.4.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 1** When 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.

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.4.(c)</td>
<td>§1735.4.(c)</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
</tbody>
</table>

(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.

<table>
<thead>
<tr>
<th>Joint Commission Standards</th>
<th>California Code of Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>MM.05.01.09 Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>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.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>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).</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>EP 4 All medications prepared in the organization are correctly labeled with the following: Expiration date when not used within 24 hours.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>EP 5 All medications prepared in the organization are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.</td>
<td>§1735.4.(c)</td>
</tr>
<tr>
<td>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.</td>
<td>§1735.4.(c)</td>
</tr>
</tbody>
</table>
§1735.5. Compounding Policies and Procedures.

(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.

(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.

(c) The policy and procedure manual shall include the following:

1. The organization complies with law and regulation.

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

3. The organization has policies and procedures that guide and support patient care, treatment, or services.

4. The organization manages the implementation of policies and procedures.

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.5.(c)(1)</td>
<td>§1735.5.(c)(1)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1735.5.(c)(2)</td>
<td>§1735.5.(c)(2)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.5.(c)(3)</td>
<td></td>
<td>HR.01.04.01 The organization provides orientation to staff.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization orient's 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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3 The organization orient's staff on the following: Relevant policies and procedures. Completion of this orientation is documented.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization orient's 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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.05.03 Staff participate in ongoing education and training.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization's education and training comply with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IC.01.02.01 Organization leaders allocate needed resources for infection prevention and control activities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3 The organization provides equipment and supplies to support infection prevention and control activities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

**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).

**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.

**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)

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.

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.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

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

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.
(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.5.(c)(5)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
</tbody>
</table>
|             |                                | 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. |
### Compounding Facilities and Equipment.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### §1735.6

§1735.6. Compounding Facilities and Equipment.

**(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.

**EC.02.06.01** The organization establishes and maintains a safe, functional environment.

- **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.

**(b)** Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

**EC.04.01.01** The organization collects information to monitor conditions in the environment.

- **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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.6.(b)</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1735.6.(c)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
</tbody>
</table>

(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.

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.7.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**§1735.7. Training of Compounding 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.

**HR.01.04.01 The organization provides orientation to staff.**

<table>
<thead>
<tr>
<th>EP 1</th>
<th>The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

| 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) |

| 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. |

| EP 2 | The organization's education and training comply with law and regulation. |

| EP 4 | Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented. |

| 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) |

| 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. |

**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. |
§1735.7.(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.

HR.01.05.03 Staff participate in ongoing education and training.

(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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.7.(b)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>

| §1735.7.(c) | HR.01.06.01 Staff are competent to perform their responsibilities. |
|            | 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. |

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.8.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Compounding Quality Assurance.

#### §1735.8.


#### §1735.8.(a)

(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.

<table>
<thead>
<tr>
<th>LD.04.01.01</th>
<th>The organization complies with law and regulation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LD.04.01.07</th>
<th>The organization has policies and procedures that guide and support patient care, treatment, or services.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LD.04.04.01</th>
<th>Leaders establish priorities for performance improvement. (Refer to the &quot;Performance Improvement&quot; (PI) chapter.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>EP 2</td>
<td>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)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MM.08.01.01</th>
<th>The organization evaluates the effectiveness of its medication management processes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 1</td>
<td>The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization analyzes data on its medication management processes.</td>
</tr>
<tr>
<td>EP 3</td>
<td>The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</td>
</tr>
<tr>
<td>EP 4</td>
<td>The organization reviews the literature and other external sources for new technologies and best practices.</td>
</tr>
<tr>
<td>EP 5</td>
<td>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.</td>
</tr>
<tr>
<td>EP 6</td>
<td>The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
</tr>
</tbody>
</table>
§1735.8.(a) 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.

Pl.01.01.01 The organization collects data to monitor its performance.

EP 1 The organization sets priorities for data collection. (See also LD.04.04.01, EP 1)

EP 2 The organization identifies the frequency for data collection.

EP 3 The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)

Pl.02.01.01 The organization compiles and analyzes data.

EP 1 The organization compiles data in usable formats.

EP 2 The organization identifies the frequency of data analysis.

EP 4 The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.

EP 5 The organization compares data with external sources, when available.

EP 8 The organization uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5; Pl.03.01.01, EP 1)

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.

§1735.8.(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.

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.
**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 14-16)

**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.

---

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.8.(c)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD.04.04.01</td>
<td>Leaders establish priorities for performance improvement. (Refer to the &quot;Performance Improvement&quot; (PI) chapter.)</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>MM.08.01.01</td>
<td>The organization evaluates the effectiveness of its medication management processes.</td>
<td>EP 1 The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization analyzes data on its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</td>
<td></td>
</tr>
<tr>
<td>§1735.8.(d)</td>
<td></td>
<td>LD.04.04.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>
### 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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1735.8(d)</td>
<td></td>
<td>PI.02.01.01 The organization compiles and analyzes data.</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PI.03.01.01 The organization improves performance.</td>
<td>EP 4 The organization takes action when it does not achieve or sustain planned improvements.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§4123.</td>
<td>Compounding Drug for Other Pharmacy for Parenteral Therapy</td>
<td>§4123.</td>
<td>LD.01.01.01 The organization has a leadership structure.</td>
</tr>
<tr>
<td></td>
<td>§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.</td>
<td>EP 2 Governance identifies those responsible for planning, management, and operational activities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3 Governance identifies those responsible for the provision of care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.01.03.01 Governance is ultimately accountable for the safety and quality of care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 1 Governance defines in writing its responsibilities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 3 Designated leaders approve contractual agreements.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 4 Leaders monitor contracted services by establishing expectations for the performance of the contracted services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 6 Leaders monitor contracted services by evaluating these services in relation to the organization's expectations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 7 Leaders take steps to improve contracted services that do not meet expectations. Note: Examples of improvement efforts to consider include the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Increase monitoring of the contracted services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Provide consultation or training to the contractor.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Renegotiate the contract terms.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Apply defined penalties.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Terminate the contract.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 8 When contractual agreements are renegotiated or terminated, the organization maintains the continuity of patient care.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§4127</td>
<td>§4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**§4127.1. Pharmacies that Compound Sterile Injectable Drugs**

**§4127**

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

**LD.04.01.01** The organization complies with law and regulation.

**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)** 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.

**LD.04.01.01** The organization complies with law and regulation.

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§4127.1.(b)</td>
<td>§4127.1.(b)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

| §4127.1.(d)| §4127.1.(d)                   | 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. * |
|            | (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 |

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.
to obtain a license pursuant to this section.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§4127.1.(d)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

§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.
§4127.2. Pharmacies that Compound Sterile Injectable Drugs

§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.

LD.04.01.01 The organization complies with law and regulation.

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) 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:

LD.04.01.01 The organization complies with law and regulation.

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) 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.

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§4127.2.(b)(1)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>§4127.2.(b)(2)</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§4127.2.(c)</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§4127.2.(d)</td>
<td>(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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
§4127.3. Pharmacies that Compound Sterile Injectable Drugs

§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.

§4127.3.(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.

§4127.3.(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.

§4127.3.(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.
§4127.4. Pharmacies that Compound Sterile Injectable Drugs

§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.
§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).
§4127.6. Pharmacies that Compound Sterile Injectable Drugs

§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.
§4127.7. Pharmacies that Compound Sterile Injectable Drugs

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:

- **§4127.7.(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.
  - **MM.05.01.07** The organization safely prepares medications.
  - **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)** An ISO class 5 cleanroom.
  - **MM.05.01.07** The organization safely prepares medications.
  - **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)** A barrier isolator that provides an ISO class 5 environment for compounding.
  - **MM.05.01.07** The organization safely prepares medications.
  - **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.
§4127.8. Pharmacies that Compound Sterile Injectable Drugs

§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 license holder be deemed to have a vested property right or interest in the license.
### Sterile Injectable Compounding; Compounding Area.

**§1751.** Sterile Injectable Compounding; Compounding Area.

**§1751.(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.

**§1751.(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)** 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.

**§1751.(b)(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.

**§1751.(b)(3)** Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.(b)(3)</td>
<td>The organization provides space for staff to perform their required work safely and accurately.</td>
<td>EQ.02.01.01</td>
<td>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</td>
</tr>
<tr>
<td>§1751.(b)(4)</td>
<td>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>§1751.(b)(5)</td>
<td>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.</td>
<td>EP 2</td>
<td>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.</td>
</tr>
<tr>
<td>§1751.(b)(6)</td>
<td>A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations.</td>
<td>EP 2</td>
<td>The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
</tr>
<tr>
<td>§1751.(b)(7)</td>
<td>There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.</td>
<td>EP 2</td>
<td>The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
</tr>
</tbody>
</table>

Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.
§1751.(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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
</table>

Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients. [Renumbered]
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
</table>

Policies and Procedures. [Renumbered]
### Sterile Injectable Recordkeeping Requirements.

**§1751.1.**

§1751.1. Sterile Injectable Recordkeeping Requirements.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.1.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**(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.

**(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:

**(1)** The training and competency evaluation of employees in sterile product procedures.

**(2)** Refrigerator and freezer temperatures.

**(3)** Certification of the sterile compounding environment.
§1751.1.(b)(3) 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.

EP 1

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.

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.

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.

§1751.1.(b)(4) Other facility quality control logs specific to the pharmacy’s policies and procedures (e.g., cleaning logs for facilities and equipment).

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.

§1751.1.(b)(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

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.

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.

MM.03.01.01 The organization safely stores medications.

EP 8 All expired, damaged, and/or contaminated medications are removed from patient care areas and stored separately from medications available for administration.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.1.(b)(5)</td>
<td>§1751.1.(b)(6)</td>
<td>EP 18 The organization periodically inspects all medication storage areas.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</td>
<td></td>
</tr>
<tr>
<td>§1751.1.(b)(6)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>§1751.1.(c)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>
### Sterile Injectable Labeling Requirements

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.2.</td>
<td>§1751.2. Sterile Injectable Labeling Requirements</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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)
(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

#### §1751.2.(b)
(b) Name and concentrations of ingredients contained in the sterile injectable product.

#### §1751.2.(c)
(c) Instructions for storage and handling.

---

**Note:** This standard is applicable to all organizations that prepare and administer medications.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.2.(d)</td>
<td>equivalent number is EC.02.02.01</td>
<td>The organization manages risks related to hazardous materials and waste.</td>
<td></td>
</tr>
</tbody>
</table>

(d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly."

**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.

(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:

1. Compounding, filling, and labeling of sterile injectable compounds.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3(a)(1)</td>
<td>[24x26]CCR Number Joint Commission California Code of Regulations Joint Commission Standards §1751.3.(a)(1) Equivalent Number</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§1751.3(a)(2)</td>
<td>[51x365]EP 6</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>[51x474]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.</td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>[80x18]§1751.3.(a)(2)</td>
<td>[80x565]EP 2</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.</td>
<td></td>
<td>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>[101x75]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.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>[128x354]The organization provides care, treatment, or services in accordance with licensure requirements, laws, administration and recommended rate of administration.</td>
<td></td>
<td>LD.04.01.07 Medications are labeled.</td>
<td></td>
</tr>
<tr>
<td>[128x565]Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td></td>
<td>EP 2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</td>
<td></td>
</tr>
<tr>
<td>[157x365]The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>[157x574]Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td>LD.04.01.07 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>[166x387]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.</td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>[212x365]The organization manages the implementation of policies and procedures.</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>[211x387]The organization manages the implementation of policies and procedures.</td>
<td></td>
<td>EP 1 Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>[230x365]Medications are labeled.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>[230x414]Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td></td>
<td>LD.04.01.07 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>[241x365]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.</td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>[270x365]Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.</td>
<td></td>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>[297x365]All medications prepared in the organization are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).</td>
<td></td>
<td>LD.04.01.07 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td>[325x428]Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>[336x18]§1751.3.(a)(3)</td>
<td>[336x414]Note: This standard is applicable to all organizations that prepare and administer medications.</td>
<td>EQ.01.05.01 The organization receives and stores medical equipment and supplies at its site(s).</td>
<td></td>
</tr>
<tr>
<td>(3) Equipment and supplies.</td>
<td></td>
<td>EP 1 The organization designates clearly identified, separate areas for storing each of the following types of equipment:</td>
<td></td>
</tr>
<tr>
<td><a href="3">347x18</a> Equipment and supplies.</td>
<td></td>
<td>- Obsolete equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Equipment requiring maintenance or repair</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Dirty equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Clean equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Patient-ready equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(See also IC.02.02.01, EP 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization maintains the cleanliness of patient-ready medical equipment. (See also IC.02.02.01, EPs 1 and 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5 The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)</td>
<td></td>
</tr>
</tbody>
</table>
EP 1 The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services. 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.

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.

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.

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.

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.

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. 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.

HR.01.04.01 The organization provides orientation to staff.

EP 1 The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3) 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.

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)

EP 3 The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3(a)(4)</td>
<td>§1751.3.(a)(4)</td>
<td>EP 4</td>
<td>The organization orientates 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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.05.03</td>
<td>Staff participate in ongoing education and training.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization's education and training comply with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§1751.3.(a)(5)</td>
<td>EC.02.02.01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages hazardous materials and waste from receipt or generation through final use or disposal.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>The organization implements its procedures in response to hazardous material and waste spills or exposures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 11</td>
<td>For managing hazardous materials and waste, the organization has the permits, licenses, manifests, and material safety data sheets required by law and regulation.</td>
</tr>
<tr>
<td>CCR Number §1751.3.(a)(6)</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------------------</td>
<td>----------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 12</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.3.(a)(6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(6) Quality assurance program.</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.04.01</td>
<td>Leaders establish priorities for performance improvement. (Refer to the &quot;Performance Improvement&quot; (PI) chapter.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>Performance improvement occurs organization-wide.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.3.(a)(6)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

**PI.01.01.01** The organization collects data to monitor its performance.

**EP 1** The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)

**EP 2** The organization identifies the frequency for data collection.

**EP 3** The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)

(7) Record keeping 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.

**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.

**RC.01.05.01** The organization retains its patient records.

**EP 1** The retention time of the patient record is determined by its use and organization policy, in accordance with law and regulation.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3.(b)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.01</td>
<td>A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.</td>
</tr>
<tr>
<td>§1751.3.(c)</td>
<td></td>
<td>EC.02.02.01</td>
<td>The organization manages risks related to hazardous materials and waste.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages hazardous materials and waste from receipt or generation through final use or disposal.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>The organization implements its procedures in response to hazardous material and waste spills or exposures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.3.(c)</td>
<td></td>
<td>MM.01.01.03</td>
<td>The organization safely manages high-alert and hazardous medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization identifies, in writing, its high-alert and hazardous medications. * Footnote *: For a list of high-alert medications, see <a href="http://www.ismp.org">http://www.ismp.org</a>. For a list of hazardous medications, see <a href="http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html">http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html</a>.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)</td>
</tr>
</tbody>
</table>

§1751.3.(d)

(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

| §1751.3.(d)(1) | 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. |

§1751.3.(d)(2)

(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.

| §1751.3.(d)(2) | HR.01.04.01 | The organization provides orientation to staff. |
|                | 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. |
|                | 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. |
|                | EP 2       | The organization's education and training comply with law and regulation. |
|                | 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. |
### §1751.3.(d)(2)

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

### §1751.3.(d)(3)

(3) Policies and procedures must address at least the following:

#### §1751.3.(d)(3)(A)

<table>
<thead>
<tr>
<th>HR.01.06.01</th>
<th>Staff are competent to perform their responsibilities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 1</td>
<td>The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td>EP 5</td>
<td>Staff competence is initially assessed and documented as part of orientation.</td>
</tr>
<tr>
<td>EP 6</td>
<td>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.</td>
</tr>
</tbody>
</table>

#### LD.04.01.07

| 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.04.01.01

| 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. |

#### §1751.3.(d)(3)(B)

<table>
<thead>
<tr>
<th>LD.04.01.07</th>
<th>The organization has policies and procedures that guide and support patient care, treatment, or services.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 1</td>
<td>Leaders review and approve policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LD.04.01.01</th>
<th>The organization complies with law and regulation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>§1751.3.(d)(3)(B)</td>
<td>[Link]</td>
</tr>
</tbody>
</table>
| | | 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.03.01.01 | The organization safely stores medications. |
| | | EP 2 | The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. |
| §1751.3.(d)(3)(C) | [Link] | 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. |
| | | MM.03.01.01 | The organization safely stores medications. |
| | | EP 2 | The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. |
| §1751.3.(d)(3)(D) | [Link] | 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. |
### §1751.3.(d)(3)(E)

- **Personnel access and movement of materials into and near the controlled area.**

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3.(d)(3)(E)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
</tbody>
</table>
| | | 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. |
| | | EQ.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. |

### §1751.3.(d)(3)(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).**

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3.(d)(3)(F)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
</tbody>
</table>
| | | 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.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. |

### §1751.3.(d)(3)(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.**

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3.(d)(3)(G)</td>
<td></td>
<td>EQ.01.05.01</td>
<td>The organization receives and stores medical equipment and supplies at its site(s).</td>
</tr>
</tbody>
</table>
| | | 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) |
<table>
<thead>
<tr>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 3</td>
<td>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)</td>
</tr>
<tr>
<td>EP 4</td>
<td>The organization maintains the cleanliness of patient-ready medical equipment. (See also IC.02.02.01, EPs 1 and 4)</td>
</tr>
<tr>
<td>EP 5</td>
<td>The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)</td>
</tr>
<tr>
<td>EQ.02.01.01</td>
<td>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</td>
</tr>
<tr>
<td>IC.01.05.01</td>
<td>The organization plans for preventing and controlling infections.</td>
</tr>
<tr>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>IC.02.01.01</td>
<td>The organization implements the infection prevention and control activities it has planned.</td>
</tr>
<tr>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>EP 2</td>
<td>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 <a href="http://www.cdc.gov/ncidod/dhqp/">http://www.cdc.gov/ncidod/dhqp/</a> (Infection Control in Healthcare Settings).</td>
</tr>
<tr>
<td>IC.02.02.01</td>
<td>The organization reduces the risk of infections associated with medical equipment, devices, and supplies.</td>
</tr>
<tr>
<td>EP 1</td>
<td>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 <a href="http://www.cdc.gov/ncidod/dhqp/sterile.html">http://www.cdc.gov/ncidod/dhqp/sterile.html</a> (Sterilization and Disinfection in Healthcare Settings).</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>§1751.3.(d)(3)(G)</td>
<td></td>
</tr>
<tr>
<td>§1751.3.(d)(3)(H)</td>
<td></td>
</tr>
</tbody>
</table>

**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.

**EC.02.02.01** The organization manages risks related to hazardous materials and waste.

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)

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.02.01.01** The organization implements the infection prevention and control activities it has planned.

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 contract, 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).

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.3.(d)(3)(H)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.3.(d)(3)(I)</td>
<td>(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.</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.3.(d)(3)(J)</td>
<td>(J) Sterilization.</td>
<td>IC.01.02.01</td>
<td>Organization leaders allocate needed resources for infection prevention and control activities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization provides access to information needed to support infection prevention and control activities. (See also IM.02.02.03, EP 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1751.3.(d)(3)(K)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
</tbody>
</table>

(K) End-product evaluation and testing.

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.
§1751.4. Facility and Equipment Standards for Sterile Injectable Compounding.

**(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.

**(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.

**(c)** All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
The organization makes space and equipment available as needed for the provision of care, treatment, or services. The arrangement and allocation of space supports safe, efficient, and effective care, treatment, or services. The leaders provide for equipment, supplies, and other resources.

The organization receives and stores medical equipment and supplies at its site(s). The organization maintains the cleanliness of all storage areas. (See also IC.02.02.01, EP 4)

The organization complies with law and regulation.

The organization has policies and procedures that guide and support patient care, treatment, or services. Leaders review and approve policies and procedures that guide and support patient care, treatment, or services. 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.

The organization manages the implementation of policies and procedures.

The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services. The organization documents the performance of these checks. 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.

The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.

The organization complies with law and regulation.

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

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 Cabinety, 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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.4(e)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td>MM.05.01.07</td>
<td>MM.05.01.07</td>
<td>The organization safely prepares medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>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.</td>
</tr>
</tbody>
</table>
§1751.5. Sterile Injectable Compounding Attire.

§1751.5. Sterile Injectable Compounding Attire.

(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.

(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

(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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.5.(b)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.5.(b)(1)</td>
<td>IC.01.02.01</td>
<td>Organization leaders allocate needed resources for infection prevention and control activities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization provides equipment and supplies to support infection prevention and control activities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.5.(b)(2)</td>
<td>EC.02.01.01</td>
<td>The organization manages safety and security risks.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

(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.

(2) Cleanroom garb must be donned and removed outside the designated area.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.5.(b)(3)</td>
<td>§1751.5.(b)(3)</td>
<td>EC.02.01.01</td>
<td>The organization manages safety and security risks.</td>
</tr>
<tr>
<td></td>
<td>(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.</td>
<td>EP 3</td>
<td>The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.5.(b)(4)</td>
<td>§1751.5.(b)(4)</td>
<td>EC.02.01.01</td>
<td>The organization manages safety and security risks.</td>
</tr>
<tr>
<td></td>
<td>(4) Head and facial hair must be kept out of the critical area or be covered.</td>
<td>EP 3</td>
<td>The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IC.01.02.01</td>
<td>Organization leaders allocate needed resources for infection prevention and control activities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization provides equipment and supplies to support infection prevention and control activities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.5.(b)(5)</td>
<td>§1751.5.(b)(5)</td>
<td>EC.02.01.01</td>
<td>The organization manages safety and security risks.</td>
</tr>
<tr>
<td></td>
<td>(5) Gloves made of low-shedding materials are required.</td>
<td>EP 3</td>
<td>The organization takes action to minimize identified safety and security risks. Note: In the patient's home, actions may be limited to education.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1751.5.(b)(5)</td>
<td>[24x26]</td>
<td>[52x354]</td>
<td>[73x365]</td>
</tr>
<tr>
<td></td>
<td><strong>LD.04.01.01</strong> The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>LD.04.01.07</strong> The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 1</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>EP 2</strong> The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**§1751.5.(c)**

(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.
§1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

(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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6.</td>
<td></td>
<td>§1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.</td>
<td></td>
</tr>
<tr>
<td>§1751.6.(a)</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization implements its written processes for medication self-administration or medication administration.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PC.02.03.01 The organization provides patient education and training based on each patient’s needs and abilities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- An explanation of the plan for care, treatment, or services</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Procedures to follow if care, treatment, or services are disrupted by a natural disaster or emergency</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Basic health practices and safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on the safe and effective use of medications. (See also MM.06.01.01, EP 9; MM.06.01.03, EPs 3-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Nutrition interventions (for example, supplements) and modified diets</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Infection prevention and control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Discussion of pain, the risk for pain, the importance of effective pain management, the pain assessment process, and methods for pain management</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on personal hygiene and grooming</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on oral health</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Basic physical and structural home safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on the safe and effective use of medical equipment or supplies provided by the organization</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on the storage, handling, and access to medical gases and supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on the identification, handling, and safe disposal of hazardous medications and infectious wastes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Habilitation or rehabilitation techniques to help the patient reach maximum independence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information on the use of restraint</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(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.

(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.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
California Compounding Pharmacy Crosswalk
California Code of Regulations to 2010 Joint Commission Standards & EPs

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6(e)</td>
<td>(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.6(e)(1)</td>
<td>(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:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.6(e)(1)(A)</td>
<td>(A) Aseptic technique.</td>
<td>HR.01.05.03 Staff participate in ongoing education and training.</td>
<td>EP 1 Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.06.01 Staff are competent to perform their responsibilities.</td>
<td>EP 2 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 3 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 5 Staff competence is initially assessed and documented as part of orientation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

California Compounding Pharmacy Crosswalk Wednesday, July 7, 2010 © 2010 The Joint Commission on Accreditation of Healthcare Organizations
§1751.6.(e)(1)(A) Equivalent Number: HR.01.05.03
Staff participate in ongoing education and training.

(B) Pharmaceutical calculations and terminology.

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.

§1751.6.(e)(1)(C) Equivalent Number: HR.01.05.03
Staff participate in ongoing education and training.

(C) Sterile product compounding documentation.

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6.(e)(1)(C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| | EP 3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assessment 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. |
| | §1751.6.(e)(1)(D) HR.01.05.03 Staff participate in ongoing education and training. |
| (D) Quality assurance procedures. | 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. |
<p>| | 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. |</p>
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6.(e)(1)(D)</td>
<td>[24x26]</td>
<td>[51x354]</td>
<td>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</td>
</tr>
<tr>
<td></td>
<td>[24x26]</td>
<td>[51x387]</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td>[24x26]</td>
<td>[35x354]</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td>[24x26]</td>
<td>[35x354]</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td>[24x26]</td>
<td>[35x354]</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>[24x26]</td>
<td>[35x354]</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

| §1751.6.(e)(1)(E) | HR.01.05.03 Staff participate in ongoing education and training. |
| | (E) Aseptic preparation procedures. |
| | 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. |
### §1751.6.(e)(1)(E) Equivalent Number

**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.

### §1751.6.(e)(1)(F)

**HR.01.05.03** Staff participate in ongoing education and training.

(F) Proper gowning and gloving technique.

**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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6.(e)(1)(G)</td>
<td></td>
<td>HR.01.05.03</td>
<td>Staff participate in ongoing education and training.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.06.01</td>
<td>Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>Staff competence is initially assessed and documented as part of orientation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 6</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 16</td>
<td>The organization maintains copies of competency assessments for personnel who provide services.</td>
</tr>
<tr>
<td>§1751.6.(e)(1)(H)</td>
<td></td>
<td>HR.01.05.03</td>
<td>Staff participate in ongoing education and training.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.06.01</td>
<td>Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(G) General conduct in the controlled area.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1751.6.(e)(1)(H)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| | | 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. |
| | | HR.01.05.03 | Staff participate in ongoing education and training. |
| | §1751.6.(e)(1)(l) | | |
| | | (l) Sterilization techniques. |
| | | 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. |
<p>| | | 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. |</p>
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.6(e)(1)(i)</td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.6(e)(1)(J)</td>
<td></td>
<td>HR.01.05.03</td>
<td>Staff participate in ongoing education and training.</td>
</tr>
<tr>
<td></td>
<td>(J)</td>
<td>EP 1</td>
<td>Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR.01.06.01</td>
<td>Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>Staff competence is initially assessed and documented as part of orientation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 6</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 16</td>
<td>The organization maintains copies of competency assessments for personnel who provide services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>----------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>§1751.6.(e)(1)(J)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.6.(e)(2)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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.

- **HR.01.04.01** The organization orients staff on the following: Relevant policies and procedures. Completion of this orientation is documented.

- **HR.01.05.03** Staff participate in ongoing education and training.

- **HR.01.06.01** Staff are competent to perform their responsibilities.

- **HR.01.06.01** The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.

- **HR.01.06.01** The organization uses assessment methods to determine the individual’s competence in the skills being assessed.

- **HR.01.06.01** An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.

- **HR.01.06.01** 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.

- **HR.01.06.01** Staff competence is initially assessed and documented as part of orientation.

- **HR.01.06.01** 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.

- **HR.01.06.01** The organization maintains copies of competency assessments for personnel who provide services.

- **LD.04.01.01** The organization complies with law and regulation.

- **LD.04.01.07** The organization has policies and procedures that guide and support patient care, treatment, or services.

- **LD.04.01.07** The organization manages the implementation of policies and procedures.
§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

(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:

**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.

**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.
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.

The organization takes action on improvement opportunities identified as priorities for its medication management processes.

The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.

The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.

**PI.01.01.01** The organization collects data to monitor its performance.

The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)

The organization identifies the frequency for data collection.

The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)

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).

**PI.02.01.01** The organization compiles and analyzes data.

The organization compiles data in usable formats.

The organization identifies the frequency of data analysis.

The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.

The organization compares data with external sources, when available.

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.

Leaders prioritize the identified improvement opportunities. (See also PI.02.01.01, EP 8)

The organization takes action on improvement priorities.

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.

The organization takes action when it does not achieve or sustain planned improvements.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.7.(a)(1)</td>
<td></td>
<td>EQ.02.01.01</td>
<td>The organization maintains, tests, and inspects medical equipment used by staff in the provision of care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.08.01.01</td>
<td>The organization evaluates the effectiveness of its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization analyzes data on its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>The organization reviews the literature and other external sources for new technologies and best practices.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 6</td>
<td>The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7</td>
<td>The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 8</td>
<td>The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</td>
</tr>
<tr>
<td>§1751.7.(a)(2)</td>
<td></td>
<td>MM.03.01.01</td>
<td>The organization safely stores medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7</td>
<td>All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 18</td>
<td>The organization periodically inspects all medication storage areas.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.08.01.01</td>
<td>The organization evaluates the effectiveness of its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization analyzes data on its medication management processes.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.7.(a)(2)</td>
<td>Saving the lives of people</td>
<td>EP 3 The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization reviews the literature and other external sources for new technologies and best practices.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 6 The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7 The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 8 The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</td>
<td></td>
</tr>
<tr>
<td>§1751.7.(a)(3)</td>
<td>Actions to be taken in the event of a drug recall.</td>
<td>MM.05.01.17 The organization follows a process to retrieve recalled or discontinued medications.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§1751.7.(a)(4)</td>
<td>Written justification of the chosen expiration dates for compounded sterile injectable products.</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>§1751.7.(b)</td>
<td>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,</td>
<td>HR.01.06.01 Staff are competent to perform their responsibilities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization uses assessment methods to determine the individual's competence in the skills being assessed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
**§1751.7.(b)**

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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.7.(b)</td>
<td></td>
<td>EP 5 Staff competence is initially assessed and documented as part of orientation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 16 The organization maintains copies of competency assessments for personnel who provide services.</td>
<td></td>
</tr>
</tbody>
</table>

**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. |                                |
|                | 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. |                            |

**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. |                                |

**§1751.7.(c)**

(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.

**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. |                                |
|                | 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. |                            |

**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.08.01.01** The organization evaluates the effectiveness of its medication management processes.

<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) |                                |
|                | 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. |                                |</p>
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.7.(c)</td>
<td>California Code of Regulations</td>
<td>EP 6</td>
<td>The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7</td>
<td>The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 8</td>
<td>The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</td>
</tr>
<tr>
<td>§1751.7.(d)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>MM.05.01.07</td>
<td>The organization safely prepares medications.</td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>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.</td>
</tr>
<tr>
<td>MM.08.01.01</td>
<td>The organization evaluates the effectiveness of its medication management processes.</td>
<td>EP 1</td>
<td>The organization collects data on the performance of its medication management processes. (See also PI.01.01.01, EPs 14 and 15)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization analyzes data on its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 3</td>
<td>The organization compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>The organization reviews the literature and other external sources for new technologies and best practices.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 5</td>
<td>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.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>§1751.7.(d)</td>
<td></td>
<td>EP 6</td>
<td>The organization takes action on improvement opportunities identified as priorities for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 7</td>
<td>The organization evaluates its actions to confirm that they resulted in improvements for its medication management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 8</td>
<td>The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained.</td>
</tr>
</tbody>
</table>
### Sterile Injectable Compounding Reference Materials.

**§1751.8.**

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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.8</td>
<td></td>
<td>LD.03.03.01</td>
<td>Leaders use organization-wide planning to establish structures and processes that focus on safety and quality.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4</td>
<td>Leaders provide the resources needed to support the safety and quality of care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>------------------------------------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>

Wednesday, July 7, 2010
Page 101 of 120
Report Generated by DivSSM
© 2010 The Joint Commission on Accreditation of Healthcare Organizations
§1751.10. Furnishing to Parenteral Patient at Home.

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.
§1751.11. Furnishing to Home Health Agencies and Licensed Hospices.

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.

LD.04.01.01 The organization complies with law and regulation.

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.05.01.11 The organization safely dispenses medications.

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.

MM.05.01.13 The organization safely obtains medications when the pharmacy is closed.

EP 1 The organization has a process for providing medications to meet patient needs when the pharmacy is closed.

EP 7 The organization implements its process for providing medications to meet patient needs when the pharmacy is closed.

§1751.11.(a)

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

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.

MM.01.01.03 The organization safely manages high-alert and hazardous medications.

EP 3 The organization implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 1)
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(a)(1)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(1) furnished by a registered pharmacist;</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§1751.11.(a)(2)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1751.11.(a)(3)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>

* California Compounding Pharmacy Crosswalk
* California Code of Regulations to 2010 Joint Commission Standards & EPs
* Report Generated by DivSSM
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
</table>
| §1751.11.(a)(3) |                               | 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.(a)(4) |                               | 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. |

| §1751.11.(a)(5) |                               | 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.05.01.09 | Medications are labeled. Note: This standard is applicable to all organizations that prepare and administer medications. |
| 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. |
| 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. |

<p>| §1751.11.(a)(5) |                               | 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. |</p>
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(a)(5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.03.01.01</td>
<td>The organization safely stores medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
</tr>
<tr>
<td>§1751.11.(b)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(b)(2)</td>
<td>1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(2)</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(3)</td>
<td>(3) two vials of urokinase 5000 units;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(3)</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)</td>
<td>(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:</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(A)</td>
<td>(A) heparin sodium lock flush 100 units/mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(B)</td>
<td>(B) heparin sodium lock flush 10 units/mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(C)</td>
<td>(C) epinephrine HCl solution 1:1000;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(D)</td>
<td>(D) epinephrine HCl solution 1:10,000;</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(E)</td>
<td>(E) diphenhydramine HCl 50mg/mL;</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(F)</td>
<td>(F) methylprednisolone 125mg/2mL;</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(G)</td>
<td>(G) normal saline, preserved, up to 30 mL vials;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(H)</td>
<td>(H) naloxone 1mg/mL 2 mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(I)</td>
<td>(I) droperidol 5mg/2mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(b)(4)(J)</td>
<td>The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(J) prochlorperazine 10mg/2mL;</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>§1751.11.(b)(4)(K)</td>
<td>The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(K) promethazine 25mg/mL;</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>§1751.11.(b)(4)(L)</td>
<td>The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td>(L) dextrose 25gms/50mL;</td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(M)</td>
<td>(M) glucagon 1mg/mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(N)</td>
<td>(N) insulin (human) 100 units/mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(O)</td>
<td>(O) bumetamide 0.5mg/2mL;</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>----------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>§1751.11.(b)(4)(P)</td>
<td>(P) furosemide 10mg/mL;</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.11.(b)(4)(P)</td>
<td>(P) EMLA Cream 5 gm tube;</td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td>EP 1</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.11.(b)(4)(Q)</td>
<td>(Q) EMLA Cream 5 gm tube;</td>
<td>LD.04.01.01</td>
<td>The organization complies with law and regulation.</td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.11.(b)(4)(Q)</td>
<td>(Q) Lidocaine 1 percent 30mL vials.</td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td>EP 1</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
§1751.11.(b)(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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(b)(5)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>

§1751.11.(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(c)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>

§1751.11.(c)(1) Implement and maintain policies and procedures for:

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(c)(1)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td>§1751.11.(c)(1)(A)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MM.03.03.01 The organization safely stores medications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.11.(c)(1)(B)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MM.06.01.01 The organization safely administers medications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§1751.11.(c)(1)(C)</td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.
The organization has policies and procedures that guide and support patient care, treatment, or services.

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.

The organization manages the implementation of policies and procedures.

The organization complies with law and regulation.

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

The organization has policies and procedures that guide and support patient care, treatment, or services.

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.

The organization manages the implementation of policies and procedures.

The organization complies with law and regulation.

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

The organization has policies and procedures that guide and support patient care, treatment, or services.

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.

The organization manages the implementation of policies and procedures.

The organization complies with law and regulation.

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

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.
<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(e)</td>
<td></td>
<td>LD.04.01.07</td>
<td>The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2</td>
<td>The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td>MM.04.01.01</td>
<td>Medication orders or prescriptions are clear and accurate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 11</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 13</td>
<td>The organization implements its written processes for medication orders or prescriptions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MM.05.01.01</td>
<td>A pharmacist reviews the appropriateness of all medication orders or prescriptions for medications to be dispensed in the organization.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 1</td>
<td>For organizations that provide pharmacy services, a pharmacist reviews all medication orders or prescriptions prior to dispensing, in accordance with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PC.02.01.03</td>
<td>The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 1</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 3</td>
<td>The organization consults with the prescribing physician as needed to confirm the physician's order(s).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 4</td>
<td>The organization reviews orders and prescriptions for appropriateness and accuracy before providing care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 5</td>
<td>Prior to implementing an order or prescription, staff obtain answers to any questions that exist. (See also MM.05.01.01, EP 11)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RC.02.03.07</td>
<td>Qualified staff receive and record verbal orders.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2</td>
<td>Only authorized staff receive and record verbal orders.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 3</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
§1751.11.(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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(f)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.19 The organization safely manages returned medications.</td>
<td>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 4 The organization implements its process for managing unused, expired, or returned medications.</td>
</tr>
</tbody>
</table>

§1751.11.(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(g)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.19 The organization safely manages returned medications.</td>
<td>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EP 4 The organization implements its process for managing unused, expired, or returned medications.</td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.11.(h)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.19 The organization safely manages returned medications.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization implements its process for managing unused, expired, or returned medications.</td>
<td></td>
</tr>
</tbody>
</table>

§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.

<table>
<thead>
<tr>
<th>CCR Number</th>
<th>California Code of Regulations</th>
<th>Joint Commission Equivalent Number</th>
<th>Joint Commission Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1751.11.(i)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MM.05.01.19 The organization safely manages returned medications.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1 The organization determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the organization.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 4 The organization implements its process for managing unused, expired, or returned medications.</td>
<td></td>
</tr>
<tr>
<td>CCR Number</td>
<td>California Code of Regulations</td>
<td>Joint Commission Equivalent Number</td>
<td>Joint Commission Standards</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>§1751.12.</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1751.12.(a)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
<tr>
<td>§1751.12.(b)</td>
<td></td>
<td>LD.04.01.01 The organization complies with law and regulation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD.04.01.07 The organization has policies and procedures that guide and support patient care, treatment, or services.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2 The organization manages the implementation of policies and procedures.</td>
<td></td>
</tr>
</tbody>
</table>
Community Health Accreditation Program (CHAP)
March 26, 2010

Debbie Anderson
Site Licensing Manager
California State Board of Pharmacy
1625 N. Market Blvd. Suite N219
Sacramento, CA 95834

Dear Debbie,

The Community Health Accreditation Program (CHAP) is delighted to provide this application for renewal of our approval by the California State Board of Pharmacy as an accrediting agency. The following document and attachments address all of the criteria which you have shared with us. We are eager to discuss our application, answer any questions or provide any needed clarification, and look forward to continuing our relationship in support of quality and safety.

1. Periodic Inspection-CHAP policies require a site visit, with a minimum frequency of every 3 years. Please see our policies attached for further information. ATTACHMENT A Accreditation Policy D2 and Site Visit Policy D5

2. Documented accreditation standards-CHAP has created accreditation Standards of Excellence for Pharmacy which reflect California law and the latest best practice information in the industry, as well as Medicare Supplier and Quality Standards. All organizations seeking CHAP accreditation are also assessed against CHAP's CORE standards. ATTACHMENT B Standards of Excellence for Core and Pharmacy

3. Evaluation of surveyor’s qualifications-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 receive a 5 day classroom
orientation and 4-6 site visits where they are assigned an experienced pharmacy site visitor preceptor. ATTACHMENT C Site Visitor Job Description, Introductory Site Visitor Evaluation, Annual Performance Evaluation

4. **Acceptance by major California payers**-CHAP is accepted by major payers everywhere. CHAP works effectively and ongoing with all payers to educate them about CHAP, and the robustness of the accreditation process.

5. **Unannounced inspections of CA accredited sites**-CHAP has 6 currently accredited pharmacy sites in CA, and over 90 total sites nationally. Our agreement with these organizations includes allowing oversight visits for organizations who monitor CHAP performance. CHAP welcomes this oversight and opportunity for learning, continuous improvement and accountability.

6. **Board access to accreditor's report on individual pharmacies**-CHAP agreements allow CHAP to disclose accreditation reports to certain authorities, which would include the CA Board of Pharmacy. CHAP standards also required accredited organizations to disclose this information. Each CHAP organization has a copy of the written report available on site. A process for providing reports on demand can be established.

7. **Length of time the accrediting agency has been operating**-CHAP was founded in 1965, as the first organization in the United States to accredit community based health care organizations. CHAP is authorized by the Centers for Medicare and Medicaid Services (CMS) to provide accreditation for home health, hospice, durable medical equipment and pharmacy.

8. **Ability to accredit out of state pharmacies**-As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and the US Territories.

Debbie, I believe this information is responsive to your email request of March 23, 2010. We are eager to renew our approval as an accreditation agency for pharmacies that compound injectible sterile drug products by the California Board of Pharmacy. We look forward to your feedback after your April 2010 board meeting. Please do not hesitate to contact me with any questions or concerns at 202-862-3413.

Sincerely,

Terry A. Duncombe
President and CEO

CHAP
ACCREDITATION POLICY

Policy
Accreditation is the systematic process by which home and community-based providers of health care services and products are evaluated. The accreditation process includes a 3 year contract cycle with a site visit at least every 3 years. The CHAP Standards of Excellence are the parameters by which organizations are measured. For Deemed Organizations, the Medicare Conditions of Participation are also built into CHAP Standards of Excellence, and are cited separately.

See Policy D.3 for further information on Accreditation with Deemed Status.

The accreditation process promotes the coordination and integration of quality health care delivery by all types of providers. It promotes the best possible use of available health personnel and products, and fosters a climate for ongoing self-study and improvement. CHAP Accreditation distinguishes the excellent organization from its competition because knowledgeable peers from across the country have judged it to have met the CHAP Standards of Excellence. This process identifies for the consumer those organizations that have measurable quality indicators for structure, process, and outcomes.

Procedure
The process of accreditation includes the following steps:
1. Submission of a CHAP application with non-refundable application fee
2. Signing of a three year contract (a 30 day review period is allowed by CHAP)
3. Assignment of each provider organization to a Customer Relations Representative, who is their main point of contact and support at CHAP
4. Submission of a Self Study (three months is allowed for its completion; extensions can be granted upon written request from the provider organization)
5. A site visit will be conducted after the submission of the completed Self-Study Report; with scheduling based self study received date.
6. Submission of an acceptable Plan of Correction for each Medicare deficiency and/or CHAP citation identified during the site visit.
7. Most documents can be completed electronically
8. Final accreditation determinations from the Board of Review (See BOR Policy-F1)
9. The accreditation period will be 3 years. This period begins with the date the acceptable Plan of Correction (if required) is submitted to CHAP, for initial organizations. For continuing organizations, the accreditation period begins the day following the end of the previous accreditation cycle.
10. On rare occasions, CHAP may adjust accreditation periods, and grant accreditation extensions, when necessary.
11. Written notification of provider of final accreditation results, including an Accreditation Report.
   a. Accreditation types include:
      • Accreditation without Required Actions
      • Accreditation with Required Actions
      • Accreditation with Required Actions & Focus Visit
      • Accreditation with Required Actions & Progress Report
      • Accreditation with Required Actions, Progress Report and Focus Visit
      • Defer Accreditation
      • Deny Accreditation
      • Withdrawal of Accreditation

12. Recognition of provider accreditation through CHAP accreditation certificate and posting on CHAP web site as accredited provider

13. Consultation with CHAP staff for training or questions may occur at any point in the cycle

14. Special circumstances:
   a. **Abort:** If Site Visitors arrive for an initial visit and active patient census of other requirements are not met, the visit will be aborted (terminated without completion); the agency will go to the bottom of the scheduling list, and the Site Visit day will be billed
   b. **Defer:** If Site Visitors arrive for an initial visit, and significant operational or care issues are found, yet the Site Visitors determines that the organization demonstrates willingness and ability to make changes needed to come into compliance with CHAP Standards of Excellence, the Site Visit will be completed and the BOR process will occur. The accreditation decision will be deferred, and the organization will be asked to implement corrective actions, and notify CHAP of readiness for another visit. CHAP allows 6 months for this process. Additional Site Visit fees will apply. If significant operational or care issues are identified at the subsequent visit, accreditation will be denied.

   c. **Withdrawal or termination of accreditation:** will occur if the following:
      • To demonstrate compliance with all Conditions of Participation after a condition level deficiency is cited
      • To prepare an acceptable Plan of Correction
      • Failure to make payment for accreditation services or site visits
      • These providers will be notified in writing of the denial/termination and informed of their opportunity to reapply for accreditation with CHAP or with another organization.
SITE VISITS

Purpose:
To determine the organization's current level of compliance with the CHAP accreditation standards and eligibility for initial or ongoing accreditation. To gather data through on site methods by site visitors, incorporating home visits, staff interviews, clinical, personnel and administrative record reviews, to determine the effectiveness of corrective actions implemented by an accredited organization.

Policy
1. CHAP performs site visits to organizations at various times in the accreditation cycle. The following table illustrates types of visits and related information.

<table>
<thead>
<tr>
<th>Visit Type</th>
<th>Timing</th>
<th>Standards Reviewed</th>
<th>CARES Visit Loading</th>
<th>CMS Docs (1572, etc.)</th>
<th>ASSURE/DEMETIS Database?</th>
<th>CMS Schedule</th>
<th>CHAP Docs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive</td>
<td>Initially and Every 36 months</td>
<td>Core Service Specific</td>
<td>All CORE and Service Specific Standards</td>
<td>Standard Survey</td>
<td>Yes</td>
<td>Yes</td>
<td>POC Accred Letter</td>
</tr>
<tr>
<td>Core Only (Florida)</td>
<td>1-4 months after Self Study submitted</td>
<td>Core</td>
<td>Modified</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>POC Accred Letter</td>
</tr>
</tbody>
</table>

Follow-Up:

<p>| a. COMPLAINT                | PRN                              | Core Service Specific | Modified CORE       | Only if IU             | Yes                      | No          | POC Accred Letter |
| b. ADD PRODUCT CODE         | 45 days after notification of readiness | Core Service Specific | Modified CORE       | Product Code worksheet | Yes                      | No          | POC Accred Letter |
| c. ADD SERVICE              | 1-4 months after Self Study submitted | Core Service Specific | Modified CORE       | Standard Survey        | Yes                      | Yes         | POC Accred Letter |
| d. ADD LOCATION: HH/H (NEW/ADDITIONAL PROVIDER NUMBER) OR DMEPOS | 1-4 months after organization notify CHAP of readiness | Core Service Specific | Modified CORE       | Standard Survey (HH and H only) | Yes | Yes | POC Accred Letter |</p>
<table>
<thead>
<tr>
<th>Visit Type</th>
<th>Timing</th>
<th>Standards Reviewed</th>
<th>CARES Visit Loading</th>
<th>CMS Docs (1572, etc.)</th>
<th>ASSURE/ DMEPOS Database?</th>
<th>CMS Schedule</th>
<th>CHAP Docs</th>
</tr>
</thead>
<tbody>
<tr>
<td>e. <strong>STATE MANDATED</strong></td>
<td>12 months after last scheduled site visit</td>
<td>Core Private Duty</td>
<td>Modified</td>
<td>New Jersey specific</td>
<td>No</td>
<td>No</td>
<td>POC Accred Letter</td>
</tr>
<tr>
<td>f. <strong>BOR REQUIRED</strong></td>
<td>6 months or 12 months after last site visit date</td>
<td>Former Required Actions POC with Agency Response</td>
<td>Prior Required Actions</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>POC Accred Letter</td>
</tr>
<tr>
<td>g. <strong>CHAP VALIDATION</strong></td>
<td>same as f</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. <strong>CONDITION LEVEL DEFICIENCY FOLLOW UP</strong></td>
<td>&lt; 90 days after end of visit with deficient finding</td>
<td>Standards and conditions cited</td>
<td>Modified</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>POC Accred Letter</td>
</tr>
<tr>
<td>i. <strong>HOSPICE ADDING IN-PT UNIT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. <strong>CHANGE OF OWNERSHIP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. A comprehensive visit is completed in the first year of the organization’s accreditation agreement with CHAP, and repeated every 3 years. During that visit, all standards for CORE and whichever other services for which the organization has requested accreditation are reviewed. The number of days planned for the site visit is determined by applying organization statistics to a grid.

3. In general, the number of unduplicated patient service units in a 12 month period, as well as the number of service locations, determine the number of days needed to complete a site visit.

4. All site visit days except inter-rater reliability visits and trainee days are billable to the organization.

5. The CHAP BOR Required Follow Up (Focus) Visit targets previously cited required actions and Medicare COP tag items. Clarification and verification of corrective actions taken must be quantified, analyzed and documented in detail. New findings, pertinent to the accreditation status and/or Medicare Conditions of Participation (COPs) must be addressed and documented as well, (i.e.: change in ownership, administrative personnel and operational aspects of the organization, etc.).
7. All site visits are documented in a CARES service specific workbook.

8. All visits begin with an Entrance Conference to communicate the objectives of the Site Visit, set time frames and expectations of participation by all parties, and plan the Site Visit schedule.

9. All Site Visits end with an Exit Conference, where the Site Visitor makes the Formal Presentation of findings, shares the Site Visitor recommendation for accreditation, and sets expectations for what comes next in the accreditation cycle.

10. All site visits, except Complaint and BOR Required Focus visits, must follow the Clinical Record and Home Visit Record Review guidelines.

11. Complaint visits: consultation between the RDPS and the Director of Quality and Standards to analyze the specific complaint and determine the site visit process. The RDPS will instruct the site visitor

12. BOR Required Focus visits: The RDPS will instruct the site visitor on the site visit process

13. Site visits are NOT required when a deemed home health or hospice adds a CMS approved branch office. Records from branch office clients and staff are sampled for review during the comprehensive visit, specific to each provider number.
CORE

STANDARDS OF EXCELLENCE
# TABLE OF CONTENTS

## INTRODUCTION

<table>
<thead>
<tr>
<th>PRINCIPLE</th>
<th>DESCRIPTION</th>
<th>PAGE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI.1</td>
<td>Statement of Mission</td>
<td>2</td>
</tr>
</tbody>
</table>
| CI.2      | Organizational Structure & Functional Mechanisms  
*Legal Authority, Legal Documents, Governing Body, Professional/Personal Disclosure* | 3       |
| CI.3      | Organizational Relationships/Chart | 4       |
| CI.4      | Administrative Authority & Responsibility | 5       |
| CI.5      | Organizational Policies  
*Administrative, Operational, Personnel, TB Exposure, MDA, Infection Control, Record Retention* | 6 - 8   |
| CI.6      | Communication | 9       |
| CI.7      | Ethical Issues | 10      |
| CI.8      | Research Initiatives | 11      |

## CORE II

| CII.1     | Business and Clinical Practices  
*Public Disclosure, Client Bill of Rights, Admission Information* | 13      |
| CII.2     | Client Access to Care, Services & Products | 14      |
| CII.3     | Prioritization of Care Delivery  
*Disaster/Emergency Planning* | 15      |
| CII.4     | Coordination, Planning, Implementing, Monitoring & Evaluating Care and Services Provided | 16      |
| CII.5     | Client Records | 17      |
| CII.6     | Performance Improvement | 18      |
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>PRINCIPLE</th>
<th>DESCRIPTION</th>
<th>PAGE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORE II</td>
<td>QUALITY OF SERVICES &amp; PRODUCTS</td>
<td>cont'd.</td>
</tr>
</tbody>
</table>
| CII.7     | Safety of Employees & Clients  
Regulatory Requirements, Exposure Control,  
Work Practice Controls, Education & Training,  
Safety Program, Home Assessment, Risk Management,  
MDA Reporting | 19 - 20 |
| CII.8     | Complaints | 21 |
| CORE III  | HUMAN, FINANCIAL, PHYSICAL RESOURCES | 22 |
| CIII.1    | Human Resources Support Workload Demand  
Recruitment, Assignment of Responsibilities,  
Job Descriptions, Employee Turnover,  
Organizational Climate, Exit Interviews,  
Personnel Policies & Files, Performance Evaluation,  
Orientation Plan, Staff Development,  
In-service/Continuing Education, Competency | 23-24 |
| CIII.2    | Contracts | 25 |
| CIII.3    | Financial Management  
Budget Planning Process, Capital Expenditure Plan,  
Annual External Review | 26 |
| CIII.4    | Financial Information System  
Periodic Financial Reports, Internal Financial Controls,  
Billing & Reimbursement, Payroll & Vendor Disbursements | 27 |
| CIII.5    | Physical Facilities | 28 |
| CIII.6    | Management Information System | 29 |
| CORE IV   | LONG TERM VIABILITY | 30 |
| CIV.1     | Strategic Planning  
Assessment, Organizational Needs | 31 |
| CIV.2     | Annual Evaluation of the Organization  
Process, Data, Advisory/Governing Body Review | 32 |
INTRODUCTION TO CHAP CORE STANDARDS

The Community Health Accreditation Program, Inc. (CHAP, Inc.) is an independent, non-profit accrediting body for community based health care organizations. The types of organizations accredited include: home health, hospice, public health, home care aide services, private duty services, supplemental staffing services, infusion therapy nursing, home medical equipment, pharmacy services, and community nursing centers.

This "first" accrediting body for community based health care organizations in the United States dates back to 1965. A joint venture between the American Public Health Association (APHA) and the National League for Nursing brought to fruition the futuristic view of their respective membership that accreditation was the needed mechanism to recognize excellence in community health practice. In 2001, CHAP became an independent corporation with the purpose of using the accreditation process to elevate the quality of all community-based health care in the United States.

The CHAP accreditation process utilizes the "CHAP Standards of Excellence" that are driven by considerations of management, quality, client outcomes, adequate resources and long term viability.

The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement techniques and systems
- Promote consumer satisfaction
- Affirm public trust
- Meet community health needs in a cost efficient and effective manner
- Maintain the viability of community health practice nationwide

CHAP, Inc. is committed to ensuring that home and community based health care providers adhere to the highest standards of excellence and that they maintain compliance with the current standards. Ongoing professional assistance and guidance provided by CHAP promotes continuous organizational self-improvement.

CHAP Accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and/or community based health care. Additional benefits of Accreditation by CHAP, Inc. include management consultation of the highest quality, access to a broad network of professional resources, and guidance critical to building intra- and inter-organizational collaboration and strength.
Currency and Relevance of Standards

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP, Inc. continually reviews and revises the "Standards of Excellence" to assure currency with the community health care industry. CHAP standards place a strong emphasis on organizational management and client outcomes. They are to be used as a blueprint to build and maintain a highly sophisticated home or community health care organization, thus assuring the viability of the organization.

The 2004 Edition revisions are designed to:

- Establish standards of excellence for a wide variety of home and community-based health care organizations and programs
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of individual and group consumers of home and community-based health care services
- Strengthen the long-term viability of all types of community-based health care organizations
- Advance the recognition of the importance of home and community-based health care organizations as integral components of the national health care delivery system

The re-engineered CORE Standards of Excellence address the scope and complexity of community-based health care providers in today's health care arena, are generic, and apply to all services and programs accredited by CHAP.

The core standards are used in conjunction with service specific standards to ensure compliance with:

- Federal, state and local regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

The service specific standards address requirements additional to Core which are unique to the specific service or industry.
Additional Requirements for Medicare-Certified Home Health and Hospice Services

CHAP has received authority from the Centers for Medicare and Medicaid Services (CMS) to deem certified home health services and certified hospice services to be in compliance with the Conditions of Participation (COPs). CHAP's Core/Home Health Standards and CHAP's Core/Hospice Standards contain standards which include the intent of the Medicare COPs for home health and hospice.

The home health agency that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 484 Medicare Conditions of Participation: Home Health Agencies. See Appendix I HH for a full text of the home health regulations and a cross walk to the CHAP Standards.

The hospice organization that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 418 Medicare Conditions of Participation: Hospice. See Appendix I H for a full text of the hospice regulations and a cross walk to the CHAP Standards.
Underlying Principles

I. Structure and Function

II. Quality

III. Resources

IV. Long Term Viability

Four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content.

UP I. The Organization's Structure and Function Consistently Supports Its Consumer Oriented Mission

A. Statement of Mission
B. Organizational Structure and Functional Mechanisms
C. Organizational Relationships/Chart
D. Administrative Authority and Responsibility
E. Organizational Policies
F. Communication
G. Ethical Issues
H. Research Initiatives

UP II. The Organization Consistently Provides High Quality Services and Products

A. Business and Clinical Practices
B. Client Access to Care, Services and Products
C. Prioritization of Care Delivery
D. Coordination, Planning, Implementing, Monitoring, and Evaluating Care and Services Provided
E. Client Records
F. Performance Improvement
G. Safety of Employees and Clients
H. Complaints

UP III. The Organization Has Adequate Human, Financial, and Physical Resources to Accomplish Its Stated Mission and Purpose

A. Human Resources Support Workload Demand
B. Contracts
C. Financial Management
D. Financial Information System
E. Physical Facilities
F. Management Information System
UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic Planning  
B. Annual Evaluation of the Organization

As you study and apply these standards to your own organization, give consideration to the following “THEMES” that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element – Additional statements that provide more definition of selected elements.

<table>
<thead>
<tr>
<th>Standard:</th>
<th>CI.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion:</td>
<td>CI.1a</td>
</tr>
<tr>
<td>Element:</td>
<td>1)</td>
</tr>
<tr>
<td>Sub element:</td>
<td>(a) (not all standards have sub-elements)</td>
</tr>
</tbody>
</table>

Main Sources of Evidence

<table>
<thead>
<tr>
<th>D = Documents</th>
<th>Substantiation of Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>I = Interviews</td>
<td></td>
</tr>
<tr>
<td>O = Observations</td>
<td></td>
</tr>
<tr>
<td>S = Surveys</td>
<td></td>
</tr>
<tr>
<td>Clarification</td>
<td></td>
</tr>
<tr>
<td>Verification</td>
<td></td>
</tr>
<tr>
<td>Quantification</td>
<td></td>
</tr>
</tbody>
</table>

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and to the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.
The Site Visit Report

The Site Visit Report is a legal document that states the level of compliance with the CHAP Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation: A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.

Required Action: A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.

Recommendation: A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.

Medicare Deficiencies for Home Health and Hospice Organizations:

Tag Items:

Identifiers used by CMS that indicate non-compliance with one or more Medicare Conditions of Participation or Standards are defined as Tag Items.

Tag Item designation applies only to Home Health and Hospice Organizations.

- G-Tags are specific to Home Health
- L-Tags are specific to Hospice

Tag Item designations are used in the Site Visit Report and on all CMS required documents for deemed organizations.

THE PROCESS REQUIRED TO ACHIEVE CHAP ACCREDITATION

CREATES PROFESSIONAL REWARDS FOR YOUR ORGANIZATION.
### Abbreviations

Common abbreviations used throughout the CORE Standards include:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA</td>
<td>Americans with Disabilities Act</td>
</tr>
<tr>
<td>Admin.</td>
<td>Administration</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>FDA</td>
<td>Federal Drug Administration</td>
</tr>
<tr>
<td>GB</td>
<td>Governing Board</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B Vaccine</td>
</tr>
<tr>
<td>MC</td>
<td>Medicare</td>
</tr>
<tr>
<td>MD</td>
<td>Medicaid</td>
</tr>
<tr>
<td>MDA</td>
<td>Medical Device Act</td>
</tr>
<tr>
<td>Mgmt.</td>
<td>Management</td>
</tr>
<tr>
<td>N.B.</td>
<td>&quot;Note Well&quot;</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Act</td>
</tr>
<tr>
<td>P&amp;Ps</td>
<td>Policy(ies) and Procedure(s)</td>
</tr>
<tr>
<td>TO</td>
<td>Table of Organization</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Act</td>
</tr>
</tbody>
</table>
CI.

THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORT ITS CONSUMER ORIENTED PHILOSOPHY, MISSION AND PURPOSE
CI.1

D: Current Mission statement includes a consumer focus and orientation to quality. (CI.1)

D: Consumers are defined as individuals, groups and communities. (CI.1)

D: Governing body minutes document actions taken on the Mission:
   a) Review and approval at least every 36 months
   b) Revisions and updates as applicable (CI.1b)
Published mission statements clearly identify a commitment to providing high quality services and products which address consumer needs as an organizational priority.

CL.1a Programs and services provided reflect the organization's written mission.

CL.1b The mission statement is reviewed, revised as indicated, and approved by the governing body at least every 36 months.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.2

| D: | Legal documents, specific to the organization, delineate applicable elements of CI.2b which may include: partnership agreement, articles of incorporation, bylaws, state charter, state licensure, tax license, trade name registration, business license, amendments, medicare certification and special waivers. |
| D: | Note: Governing Body may be a governmental entity. (CI.2c) |
| D & I: | Name, address, credentials and professional/business affiliation of each member is identified. (CI.2d) 
Note: Owner/Operator of a business may constitute the governing body. Governmental Boards of Health may be advisory in nature and/or may be elected or appointed officials. |
| D & I: | New member orientation is validated in writing. Governing body members describe the orientation experience and articulate key issues affecting the organization. (CI.2e) 
Note: Independent owner(s) may only have principal(s) as governing body, and orientation in CI.2e may not apply. |
| I: | Governing body members articulate responsibilities and describe the types of actions taken by the board. (CI.2f) 
Note: Selected elements may not apply to owner/operator businesses, i.e., selecting the chief administrator. |
| D: | Current signed and dated annual disclosure statements are on file for all governing body members and executive staff. (CI.2g) |
| D & I: | Governing body members confirm adherence by governing body members to legal documents which may describe notice of scheduled and special meetings, attendance requirements at meetings, appointment of officers, terms of office, committee structure and function, quorum determination. (CI.2h) |
| D: | Governing body minutes reflect agenda items, discussion, and action taken. (CI.2i) 
Note: Closed sessions are to be documented and distributed/filed per organizational policy. |

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(c), 484.14(b), 484.14(i), 484.16, 484.52. See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.52, 418.72. See Appendix IH for a full text of the regulations and a crosswalk.
CI.2a  The organization has the legal authority to operate and is in compliance with local, state and federal regulations.

CI.2b  The applicable governance structure is defined in legal documents specific to the organization.

CI.2c  An identified governing body assumes full legal authority, responsibility, and accountability for organizational performance; appoints a qualified administrator and designates advisory group membership as applicable.

CI.2d  The governing body is made up of individuals with relevant expertise, business acumen, and professional relationships specific to the stated mission of the organization.

CI.2e  Governing body members are oriented to the organization and are knowledgeable and responsive to key issues affecting the organization.

CI.2f  The governing body carries out responsibilities specific to the organization including:

1) Establishing policies consistent with organizational mission
2) Approving new and/or revised policies and procedures as indicated and necessary
3) Holding management accountable for the fiscal solvency of the organization and adequacy of financial resources
4) Approving budgets and capital expenditures
5) Selecting and evaluating the chief administrator
6) Evaluating organizational performance
7) Developing and approving strategic plan
8) Reviewing legal and business documents in light of real or potential changes to the organization on a periodic basis but not less frequently than every 36 months:
   (a) Articles of incorporation
   (b) Bylaws
   (c) Legal agreements

CI.2g  Annually, the members of the governing body and executive staff provide written disclosure of all professional or personal relationships or interests, direct or indirect that might present a conflict of interest. Statements are on file in the office.

CI.2h  The governing body complies with organizational bylaws or other legal documents.

CI.2i  Accurate, complete, and signed minutes are kept of all official meetings of the governing body, document actions taken, are distributed in accordance with organizational policy, and are retained for a minimum of five (5) years or consistent with state regulations.
CL3

D: A current organizational chart reflects lines of authority and accountability for all personnel. (Cl.3a)

D: Amendments to the organizational chart are documented as applicable. (Cl.3b)

I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (Cl.3c)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.14. See Appendix I HH for a full text of the regulations and a cross-walk.
CL3  Intra-organizational relationships are clearly defined.

CL3a  A current organizational chart delineates the lines of authority and accountability of all personnel.

CL3b  The organizational chart is reviewed and changed as needed.

CL3c  Personnel understand and use the organizational structure as outlined in the organizational chart.
Current job descriptions are on file for administrative and management positions. (CI.4a, b)

CEO/Administrator/Management resumes validate experience, knowledge, and qualifications required for the job. (CI.4b)

Note: This standard may pertain to the Chief Health Care Administrator in Public Health Organizations.

Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)

Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)

CEO/Administrative and Management personnel describe their respective areas of responsibility. (CI.4d)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(a), 484.14(c). See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c). See Appendix IH for a full text of the regulations and a crosswalk.
Authority and responsibility for overall administration and management is vested in qualified individuals.

CI.4a The chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state and federal laws.

CI.4b Qualifications for administrative and management positions are clearly defined in writing and are consistent with the scope of responsibility and the complexity of the organization, and administrative and management personnel have equivalent combinations of education, training and experience to qualify for their assigned responsibilities.

CI.4c A qualified individual is designated in writing to be administratively responsible in the absence of the chief executive/administrator.

CI.4d Administrative and management responsibilities are clearly defined and delegated as specified and include:

1) Organizing and directing the organization's ongoing operations to assure the availability and provision of care and services
2) Implementing governing body directives and organizational policies and procedures
3) Complying with applicable laws and regulations
4) Recruiting, employing, and retaining qualified personnel to maintain appropriate staffing levels
5) Ensuring adequate staff education
6) Completing performance evaluations on subordinate staff in accordance with organizational policy
7) Directing and monitoring organizational Performance Improvement activities
8) Managing operations in accordance with established fiscal parameters
9) Planning, developing, implementing, administering and evaluating programs
10) Representing the organization to other groups, organizations and the general public
11) Ensuring the accuracy of public information materials
12) Informing the governing body and staff of current organizational, community, and industry trends
Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.Sa)

Administrative policies and procedures address the areas delineated in CI.Sb.

A written safety program sets the parameters for monitoring environmental conditions and identifying potential hazards/risks in accordance with elements such as biomedical waste management, storage and handling of environmental cleaning supplies, fire safety, preventive maintenance of equipment, reporting of malfunctioning equipment, environmental controls to prevent client or staff accidents and or incidents and safety of clients and employees in the community. (CI.Sb)

Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.Sc.

Personnel policies address the 9 elements of CI.Sd.

Note: The Medicare Certified home health agency must comply with CFR 484.10(d), 484.11, 484.12(b-c), 484.14(e), 484.16, 484.18, 484.18(b-c), 484.48(a-b), 484.51, 484.52(b), 484.55. See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.
CI.5 Organizational policies and procedures reflect an emphasis on quality and ethical practice and relate directly to the mission of the organization.

CI.5a Policies and procedures are developed, revised, and reviewed annually to assure currency of information.

CI.5b Administrative policies and procedures delineate administrative authority and responsibility for governance, planning, financial control and personnel. Policies include at a minimum:

1) Written Disclosure of conflict of interest
2) Public Disclosure of information
3) Responsibilities of ethical issues review group
4) Rights and responsibilities of clients
5) Internal and External Complaint Management
6) Exposure control plan
7) Formal safety program
8) Financial policies and procedures
9) Research activities/investigational studies as applicable.

CI.5c Operational policies and procedures form the framework for planning, delivery and evaluation of care and services provided. Policies include at a minimum:

1) Non-discrimination statement addressing admission of clients to service
2) Defined criteria for the acceptance or non acceptance of clients
3) Admission, continuation of service and discharge
4) Standardized assessment process
5) Referral to other providers of care or services
6) Medical orders, verbal orders and physician oversight as applicable
7) Emergency service
8) After hours service
9) Confidentiality of protected health information
10) Emergency/disaster preparedness
11) Health, safety and security of staff during all hours of work
12) Services/products provided directly and under contract
13) Standards of practice for all disciplines as applicable
14) Standards of operation for all products as applicable
15) Infection control
16) Accepted medical term abbreviations

CI.5d Personnel policies are developed and revised in response to organizational change and include:

1) Conditions of employment
2) Respective obligations between employer and employee
3) Non-discrimination information
4) Grievance procedures
5) Employee orientation
6) Employee exit interviews
7) Maintenance of health reports and protected employee information
8) Employee record confidentiality and record retention
9) Recruitment, retention and performance evaluation of staff
CL.5 (Continued)

D: Written TB Exposure Control Plan includes the elements in CL.5e.

D: Written policy and procedure define the requirements of Medical Device Act reporting. (CL.5f)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CL.5f)

D: Written infection control policies and procedures include the elements in CL.5g.
CL.5e The organization's written TB Exposure Control Plan is in compliance with the most current Centers for Disease Control & Prevention (CDC) applicable recommendations and requirements for occupational exposure to Tuberculosis. The plan addresses:

1) Definition of employees at risk of occupational exposure to TB
2) Process for identifying suspected or confirmed cases of TB
3) Control of employee exposure when a patient is suspected/confirmed as having infectious TB
4) Provision of education and training to all employees to the hazards of exposure to TB at the time of employment and annually thereafter
5) Pre-employment and subsequent periodic TB screening of employees in accordance with written policy
6) Provision of follow up care to employees exposed to TB
7) Provision of follow up care to employees who convert to active disease
8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client
9) Provision of work practice oversight to minimize occupational exposure to TB
10) Adherence to reporting and record keeping requirements per state and federal law

CL.5f Organizational policy and procedure address the requirements of the Medical Device Act (MDA) and delineate the mechanisms for reporting incidents, which result in serious injury, illness or death.

1) Reports are filed with the Federal Drug Administration according to regulation
2) A designated person is responsible for ensuring compliance with reporting requirements
3) Criteria for designation of reportable events are clearly defined
4) Written protocols for the investigation of events are clearly defined
5) Investigative activities are initiated on a timely basis
6) Accurate documentation of findings include:
   (a) Investigative findings
   (b) Copies of reports sent to the manufacturer
   (c) Copies of reports to FDA
7) Retention and retrieval of findings and reports
8) In-service education on Medical Device Act reporting is provided to staff on an annual basis
   (a) Written curriculum outlines describe training content
   (b) Records of attendance are maintained

CL.5g Infection Control policies and procedures detail systems designed to promote the prevention and control of infections, monitor the occurrence of infections and evaluate the effectiveness of infection control practices.

1) Current infection control practices and strategies
2) Identification and investigation of breaks in technique
3) Sources of infection:
   (a) Nosocomial
   (b) Home acquired
   (c) Professional exposure
4) Types of infection
5) Modes of transmission of infection
D: Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (CL.5h).

D: Written policies and procedures define the parameters that ensure the client's right to access client record information and to release client record information. (CL.5h)

D: Written policy and procedure and local/state/federal regulations dictate the secure retention of all types of clinical records. (CL.5h)

D: Written policy and procedure details the process for release of information. (CL.5h)

I: Staff describe process for accessing policies and procedures. (CL.5f)
.6) Contributing causes of infection  
7) Data collection, analysis, and tracking and trending of findings  
8) Reporting requirements per state and federal regulations  
9) In-service education for staff  
   (a) Dates and times of programs  
   (b) Curriculum outline of training content  
   (c) Records of staff attendance  
10) Client and/or family teaching  
11) Use of personal protective equipment  
12) Accepted hand hygiene techniques  

**CI.Sh** Administrative, financial, client and personnel records are secured, retained and retrievable in accordance with a formal record retention policy that is in compliance with organizational policy and local, state and federal law.  
1) Minutes of all official meetings of the governing body are retained for a minimum of five (5) years.  
2) Client adult records are retained for a minimum of five (5) years after provision of service.  
3) Client records of minors are retained for a minimum of seven (7) years after the age of majority is reached.  
4) Mechanisms for client access and release of client records are defined.  
5) Authorization for client record documentation and entry and signature authorization and authentication for automated client record system in accordance with individual state law are defined.  
6) Process for maintaining safety and security of client records is defined.  
7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus thirty (30) years.  
8) Annual training records for exposure prone employees are retained for a minimum of three (3) years.  
9) Client records involved in litigation are retained until after settlement.  

**CI.Si** Staff members have access to policies and procedures.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.6

D: Informational materials, written in different languages are available and provided to clients/families as appropriate. (CI.6a)

I: Administrative/management personnel articulate cultural diversity in the community population and describe the organization's ability to meet special needs. (CI.6a)

I: Staff members demonstrate awareness and use of available resource materials, and clients/families verbalize knowledge of pertinent resources. (CI.6a)

I: Clients/families of different cultures acknowledge receipt of language specific materials and care provided by bi-lingual staff, family members and/or the use of interpreters as appropriate and necessary. (CI.6b)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.
### CI.6

Information is provided to clients/families identifying availability of organizational and community resources to assist in meeting client needs

<table>
<thead>
<tr>
<th>CI.6a</th>
<th>Language specific written materials, as necessary and appropriate, are available for distribution to client/families.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI.6b</td>
<td>Interpretive services are provided, as indicated and necessary, to ensure accurate communication between the client/family/caregiver and other types of health services personnel.</td>
</tr>
</tbody>
</table>
CI.7

D: Written policy delineates the make up and function of the designated group to review ethical issues. Authority may be self-vested in the governing body, in an independent entity or in an advisory group. (CI.7a, b)

I: Administrative/management/staff personnel describe the structure of the ethical group and the process for handling ethical concerns and issues. (CI.7b)

D: Meeting minutes document discussions of and actions taken by the group, as applicable. (CI.7c)
CI.7 The organization's business, clinical, disease prevention and health promotion activities are conducted according to ethical standards.

CI.7a A group of qualified professionals is designated by the governing body to review ethical issues as they arise.

CI.7b Organizational policy and procedure outlines the responsibilities of the group and delineates the process for submitting ethical concerns and issues for action.

CI.7c Meeting minutes clearly document group activities and are referred to the governing body for review and final action as indicated and necessary.
CL.8

I: Administrative/management personnel describe that careful consideration is given to providing a site for relevant research, that human subjects involved in any part of research activities provide written informed consent, and that specific parameters for protection of participants and confidentiality of personal information are clearly defined. (CL.8a)

D: Policy and procedure establish the parameters for research initiatives as applicable. (CL.8b)

D: Current research activities as applicable ensure compliance with CL.8a,b, c, d.

I: Administrative/management personnel describe current research initiatives as applicable. (CL.8c)

I: Staff describes use of research knowledge which was integrated into practice as applicable. (CL.8e)
CI.8 The organization considers requests for research in the area of community/public health as appropriate.

CI.8a A mechanism is in place for reviewing, processing, and approving internal and external research proposals.

CI.8b Organizational policy and procedure defines parameters for participation in research activities and investigative studies.

1) Research protocols, as applicable, for internally and externally sponsored activities are on file
2) Potential participants are provided with written information regarding the nature, process, and benefits of the research outcomes
3) Risks associated with the project are clearly delineated

CI.8c Organizations participating in research or investigative studies ensure that clients and staff are fully informed.

CI.8d Formal written consents for participants in research and/or investigative studies are obtained and retained on file in the organization.

CI.8e New knowledge from internal and external research is integrated into practice as applicable.
CII.

THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS
CURRENT PUBLIC DISCLOSURE POLICY


D: The Client Bill of Rights includes the elements of CII.1b.

I: Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1e)

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

D: Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information. (CII.1d)

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

I: Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful. (CII.1d)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.10(a-e), 484.12. See Appendix IHH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c). See Appendix IH for a full text of the regulations and a crosswalk.
### CII.1 The mission drives the activities of the organization and ensures public disclosure, client rights and ethical standards of business and clinical practice.

CII.1a A public disclosure policy defines the availability and accessibility of public information which includes ownership information, statement of the organization's mission, and licensure and accreditation status, as applicable.

CII.1b A written Client Bill of Rights is designed to recognize, protect, and promote the right of each client to be treated with dignity and respect.

1) Written policy and procedure defines the rights and responsibilities of clients.
2) Notice of rights is provided to clients in advance of providing pre-planned care.
3) The client is knowledgeable of the right to exercise his/her rights at any time.
4) The organization maintains documentation of compliance of distribution of required information to clients.
5) The client/client's designated representative is authorized to exercise their rights.
6) Confidentiality of the client record/data is maintained by the organization.
7) Access to care/service is based upon non-discrimination.
8) Clients are informed that they have the right to voice complaints/grievances to the organization regarding treatment/care/service without fear of discrimination or reprisal for doing so.
9) The organization provides the client the telephone number for the CHAP hot line, including the hours of operation and the purpose of the hotline to receive complaints or questions about the organization.
10) Clients are informed that they have the right to participate in the development of care and service plans.
11) Clients are informed verbally and in writing of billing and reimbursement methodologies prior to start of care and as changes occur, including fees for services/products provided, direct pay responsibilities, and notification of insurance coverage.

CII.1c Written admission documents, provided to the client or the client's representative prior to or at the time of initiation of care/service, ensure organizational compliance with the Client Bill of Rights and other regulatory requirements.

CII.1d A reasonable attempt is made and documented to ensure that the client and family understand their rights and responsibilities which are reviewed with the client prior to or at the time of initiation of care and periodically thereafter.
I: Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a)

I: Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b)

I: Professional, technical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b)

I: Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c)

O: Testing the after hours on call system validates compliance with organizational policy and procedure. (CII.2c)
**CII.2** Care, services, and products are available to and accessible by the client/client representative.

***CII.2a*** Care, services, and products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to client and/or family needs in scheduling and providing care.

***CII.2b*** Collaboration and networking with other providers enhance provision of care and services as applicable.

***CII.2c*** Supervisory and clinical/service staff demonstrate knowledge of organizational policy and procedure for ensuring delivery of care, services and products to clients.
CII.3

D: Written information distributed to clients/families address disasters/emergencies as applicable to the organization's service area. (CII.3a)

I: Clients/families are aware of their responsibilities in the event of an emergency episode. (CII.3a)

D: Staff are oriented to written protocols that ensure the safety and security of personnel. (CII.3b)

D: Disaster drills are documented as applicable to the organization. (CII.3c)

I: Administrative/management staff describe roles and responsibilities of personnel during an emergency episode. (CII.3c)

I: Staff members at all levels demonstrate awareness of responsibilities to ensure the safety of self and others. (CII.3c)

Note: The Medicare Certified hospice organization must comply with CFR 418.100. See Appendix IH for a full text of the regulations and a crosswalk.
CII.3 A geographic specific plan defines the protocols for prioritizing the delivery of care and services to clients and protects the safety of staff during disasters, emergencies and/or environmentally challenging situations.

CII.3a Detailed written instructions are given to clients and/or family members to ensure an appropriate and timely response on the part of the client and/or family in the event of a natural disaster, inclement weather, and/or other emergent event that might cause an interruption in the provision of services.

CII.3b Written protocols define management responsibilities in ensuring the safety and security of staff prior to or during an emergent event.

CII.3c Staff are knowledgeable of the practices and procedures relating to emergency preparedness responsibilities and emergent events.
CII.4

D: Client records document coordination of care activities, including planning, implementation, monitoring and evaluation of care/service as appropriate. (CII.4)

I: Clinical/service, financial, and operational staff describes collaboration and support among all disciplines and organizational divisions. (CII.4a)

O: Organizational planning meetings as available and appropriate. (CII.4a)

Note: The Medicare Certified home health agency must comply with CFR 484.14(g). See Appendix I HH for a full text of the regulations and a cross-walk.
CII.4 Inter and intra organizational coordination is evident in the planning, implementation, monitoring, and evaluation of care and services provided.

CII.4a Coordination between the clinical/service, financial, and operational components of the organization is evident.
I: Professional, technical, and support staff describe protocols that protect client/family information regarding confidentiality of information, use of travel record and transport and storage of travel record. (CII.5a).

I: Office staff describe ongoing security of client record information. (CII.5a)

I: Staff is knowledgeable of the client's right for access to and release of client information. (CII.5a)

O: Active and inactive client records are maintained in a secure area during working and non-working hours that is inaccessible to unauthorized individuals. (CII.5a)

S: Random sample of client records reviewed provides evidence of compliance with organizational policy, standards and regulatory requirements. (CII.5c,d)

O: Automated client record systems include safeguards. (CII.5e)

I: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e)

I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f)

I & O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.11, 484.14, 484.18(c), 484.48, 484.48(b), 484.52(b). See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.74, 418.74(a,b). See Appendix I IH for a full text of the regulations and a crosswalk.
CII.5 Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care and services provided, and as a resource document for billing and reimbursement.

CII.5a All protected health information or client records, hardcopy or automated, are kept confidential and are safeguarded against loss or unauthorized use in accordance with organizational policy and local, state or federal regulations.

CII.5b Clients have access to their records and are informed of the process.

CII.5c The client record documentation provides client information specific to care and services/products provided, current client status, and progress toward goals and outcomes of care.

CII.5d Entries to client record documentation is made only by authorized staff and in accordance with organizational policy and procedure.

CII.5e Automated client record systems ensure consistent and ongoing security and protection of data.

CII.5f The format for maintenance of client records is reviewed and updated as necessary.

CII.5g Organizations with alternate sites ensure consistent documentation, communication, coordination, and retrieval of significant administrative and client/family information.
CII.6

D: Data reflect measurement of quality of services outcomes. (CII.6a)

I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e)

D: A structured framework exists. (CII.6c)

D: A client satisfaction survey for the current year is available for review and includes, at a minimum, client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f)

I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (CII.6g)

D: Organizational committees and governing body minutes document reporting of trends of performance improvement findings. (CII.6h)

Note: The Medicare Certified home health agency must comply with CFR 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66, 418.66(a, b, c). See Appendix IH for a full text of the regulations and a crosswalk.
CII.6 A comprehensive Performance Improvement process integrates the organization’s mission and promotes an organizational wide approach that selects, reviews, and analyzes outcomes specific to organizational needs and the scope of services and products.

CII.6a Quality is defined and measured in terms of client/service outcomes.

CII.6b Specific outcomes are targeted for improvement or replication.

CII.6c The organization develops a structured framework for the investigation of target outcomes.

CII.6d The organization identifies outcomes to benchmark by utilizing internal standards, processes and protocols; practice or service guidelines; industry research and/or best practices.

CII.6e The organization continually evaluates progress toward outcomes and identifies new areas to improve or replicate as indicated by results of data analysis.

CII.6f A process for monitoring and measuring the satisfaction levels of clients is conducted at least annually.

CII.6g Performance Improvement findings are used to resolve identified problems, improve quality of services and products, and are incorporated into program planning, modification and/or enhancement.

CII.6h Trends of Performance Improvement findings are reported to appropriate organizational committees and the governing body.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY
ClI.7

D: Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (ClI.7a)

D: Written plans define parameters for exposure control, adherence to standard precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (ClI.7b)

D: Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: (ClI.7c)
  a) Definition of types of tasks and/or procedures that place an employee at risk for exposure.
  b) Description of job classifications in which all employees have the potential for occupational exposure.
  c) Description of job classifications in which employees have the potential for occasional exposure.
  d) Description of job classifications in which employees have no risk for occupationally related exposure.

O: Staff demonstrate adherence to standard precautions as determined by organizational policy: (ClI.7d)
  a) Use of gloves
  b) Use of and accessibility to masks and protective eyewear
  c) Use of protective gowns and aprons
  d) Hand hygiene/hand washing techniques including the use of chemical substances
  e) Techniques for minimizing needle sticks
  f) Use of puncture resistant sharps containers
  g) Proper transportation and storage of sharps
  h) Disposal of contaminated supplies and equipment on site

S: Random sample of employee records provides evidence of compliance with Hepatitis B (HBV) prophylaxis program. (ClI.7f)

I: Designated person describes procedures followed to ensure compliance with investigative requirements and protection of the rights of the employee who has experienced an occupational exposure. (ClI.7f)

D: Education and training records document compliance with training requirements. (ClI.7g)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c). See Appendix 1 HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organisation must comply with CFR 418.50(b), 418.100(c), 418.100(f). See Appendix 1H for a full text of the regulations and a crosswalk.
CII.7 The health and safety of employees and clients is promoted and enhanced through education, current application of infection control practices and implementation of appropriate safety measures.

CII.7a Adherence to State and/or Federal Occupational Health and Safety Administration (OSHA) and Centers for Disease Control & Prevention (CDC) requirements as applicable that address the health and safety of employees and clients and their protection from blood borne pathogens are validated.

CII.7b The organization implements its written Exposure Control Plan.

CII.7c The potential for occupational exposure is determined for all job classifications in accordance with state, federal and Occupational Health and Safety Administration (OSHA) mandate.

CII.7d Adherence to the use of Standard Precautions by job classification is documented.

CII.7e Adherence to work practice and engineering controls is evident in practice.

1) Physical work sites are maintained in a clean and sanitary condition
2) Use of disinfectant solutions
3) Handling, transporting, storage and processing of soiled/contaminated materials, supplies and equipment
4) Use of non-leak infectious waste containers as applicable
5) Identification and labeling of infectious waste as applicable

CII.7f Employer and employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing and include:

1) HBV vaccination and post exposure follow up program
2) Employer/employee responsibilities
3) Declination of HBV statement is signed by employees as applicable and filed in personnel health records
4) Complete and detailed documentation of all exposure events
5) Confidential records are maintained on HBV vaccination and post exposure follow up

CII.7g Education and training programs ensure that new employee orientation addresses all aspects of the Exposure Control Plan and that annual training is mandated for all exposure prone employees based on applicable job classification.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.7 (Continued)

D: Occupational exposure information is maintained in confidential records that are retained for the duration of employment plus thirty (30) years. (CII.7h)

I & O: Clinical, technical and support staff describe potential hazards in the home setting identified during the assessment of the client's living environment. (CII.7k)

D & I: Evidence exists that the organization monitors and reports information related to adverse events. Adverse events include but are not limited to:
- provision of care errors
- unusual occurrences
- vehicular crashes
- other types of accidents or injury
- safety hazards

Serious Adverse Events include but are not limited to:
- unexpected death not resulting from the client's medical condition
- loss of body part
- permanent or partial loss of body function
- blindness

Reports document data on adverse events that predispose the organization to real or potential liability.
- Data are collected within 30 days of an event
- Data are analyzed within 60 days of the event to determine underlying factors leading to the adverse event
- Performance Improvement processes, as applicable, include evidence of organizational changes subsequent to an adverse event (CII.7l)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA. (CII.7m)

I & O: Staff demonstrate knowledge of and compliance with the organizational infection control practices and procedures. (CII.7n)
CII.7h The organization demonstrates compliance with its Occupational Exposure Control policies, plan and procedures.

1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within ten (10) working days of assignments
2) Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification
3) A confidential medical evaluation and follow-up care is offered to employees who experience an occupational exposure:
   (a) Counseling
   (b) Testing of source individual if allowable under local and/or state law
   (c) Blood testing of the exposed employee with written consent, if medically indicated
4) Accurate, confidential, and timely documentation of:
   (a) Circumstances leading to exposure
   (b) Routes of exposure
   (c) Medical follow-up
   (d) Opportunity for counseling
   (e) Other related interventions as indicated and necessary

CII.7i The organization demonstrates compliance with its TB Exposure Control Plan.

CII.7j The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks.

CII.7k A routine assessment is made of the client's living environment to identify and evaluate potential safety hazards related to the physical space as applicable.

CII.7l A system is in place for monitoring and reporting information related to adverse events that endanger the health and safety of clients and/or employees and pre-dispose the organization to real or potential liability.

1) Adverse Events and Serious Adverse Events are defined in organizational policy
2) Data for all events is collected, analyzed tracked and trended as a part of risk management
3) Corrective actions are implemented and evaluated as indicated and necessary
4) Adverse event reports detail each episode and are distributed to advisory boards as applicable

CII.7m The organization demonstrates compliance with its policy and procedure for the Medical Device Act (MDA).

CII.7n The organization demonstrates compliance with its Infection Control policies and procedures.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIL.8

D: Examples of complaint documentation logs. (CIL.8a)

D: Formal documentation of investigative findings and reports as applicable. (CIL.8a)

D: Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CIL.8b)

I: Staff describes an understanding of the complaint process. (CIL.8c)

Note: The Medicare Certified home health agency must comply with CFR 484.10(b). See Appendix I HH for a full text of the regulations and a crosswalk.
CII.8 Client/ family complaints/concerns are responded to and resolved in a timely manner.

CII.8a The complaint process includes intake, investigation, and corrective action as applicable, complaint resolution, written reports, organizational trending and follow-up.

CII.8b Resolution/outcome information is communicated to the complainant.

CII.8c Staff are aware of organizational mechanisms for receiving and resolving complaints.
CIII.

THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL AND PHYSICAL RESOURCES WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION/PURPOSE
D: Policy, procedure and recruitment documents support a non-
discriminatory approach to hiring. (CIII.1a)

I&O: Interviews with staff and observation of client practice/service
validate adherence to discipline specific practice standards and
to regulatory guidelines and requirements specific
to respective areas of responsibility. (CIII.1b)

I: Staff confirm clear understanding of responsibilities and lines
of authority. (CIII.1c)

I: Management explains turnover rate variances as applicable,
and describes impact on recruitment and retention
activities. (CIII.1d)

D: Employee records validate the opportunity for a formal
exit interview for terminating employees in accordance
with organizational policy and procedure. (CIII.1e)

I: Employees validate receipt of conditions of employment and
describe the process for obtaining personnel related information.
(CIII.1f)

D: Employee files are complete and current and include documents
specific to CIII.1g. Evidence of verification of education/training
may include copies of diplomas, transcripts or telephone validation.

O: Specified personnel documents are secured in accordance with
organizational policy. (CIII.1h)

Note: The Medicare Certified home health agency must comply with
CFR 484.12(c), 484.14(c,e), 484.30(a), 484.32, 484.32(a), 484.34,
484.36(b). See Appendix I HH for a full text of the regulations
and a crosswalk.

Note: The Medicare Certified hospice organization must comply with
CFR 418.64, 418.70(a,b). See Appendix IH for a full text of the
regulations and a crosswalk.
CII.1 The organization has adequate and appropriate human resources to meet caseload and workload demands.

CII.1a A non-discriminatory recruitment and selection process, as defined in policy and procedure, is adhered to.

CII.1b Personnel are employed and assigned responsibilities commensurate with their education and experience.

CII.1c Job Descriptions for each employee category delineate lines of authority and reporting responsibilities, duties to be performed, and educational and experiential qualifications specific to the position.

CII.1d Employee turnover rates are monitored, tracked, and trended, as applicable.

CII.1e The opportunity for exit conferences are offered to terminating employees, are documented and trended, as applicable.

CII.1f Personnel policies/conditions of employment are provided to employees at the time of hire and thereafter as updates/revisions are needed.

CII.1g Evidence of the following employee information is maintained in accordance with organizational policy and regulatory guidelines.

1) Individual job qualifications
2) Verification of education/training
3) Certification for specialty areas of practice as applicable
4) Statement of formal training for non-professionals
5) Two (2) reference checks
6) Pre-employment interview(s)
7) Current license or certification as applicable
8) Validation of competency skills testing as applicable
   (a) Time of hire
   (b) Annual
9) Validation of performance evaluation at end of probation and annually
10) Validation of malpractice coverage for independent contractors
11) Validation of completion of the orientation process (new and reassigned personnel)
12) Validation of signed and dated confidentiality statements
13) Validation of in-service/continuing education participation as applicable
14) Validation of exit interview as applicable
15) Miscellaneous items per state, federal or organizational requirements
16) Criminal background checks in accordance with organizational policy and procedure and local and/or state law
17) Immigration and naturalization statement (I-9)

CII.1h Specified personnel documents and employee health reports may be retained in separate files per organization policy.
D: Annual evaluation form addresses elements of CII.I I as applicable to the job category.

I: Sample of employee and supervisory staff personnel records confirms adherence to the annual evaluation process. (CII.I I, I j)

D: A written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies. (CII.I k)

I: Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CII.I k)

I: Staff assigned to a new job classification describe their orientation to the new responsibilities. (CII.I k)

I: Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CII.I I)

O: Federally required in-services include OSHA mandated. Staff Development opportunities may include: independent study, satellite learning, specialized conferences, formal courses of study and mentoring. (CII.I I)

D & I: Policy and managers describe the process for assuring that personnel are identified. Service contracts with organizations detail the process that the sub-contract organization will assure sub-contract organization identification of staff. (CII.1m)
CIII.1i  An annual written performance evaluation process is completed on all employees by the respective supervisor and includes:

1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)
2) Achievement of previously established goals
3) On site evaluation reports/competency testing for clinical/field/service staff
4) A signed, dated validation of the evaluation process by the employee and employer representative

CIII.1j  An annual performance evaluation process provides an opportunity for active participation by employees through:

1) Employee development planning/new goal setting
2) Employee response to evaluation

CIII.1k  A written plan details the orientation process for all new and reassigned employees which addresses applicable elements pertinent to each job classification.

CIII.1l  The organization shall provide in-service and staff development as needed and as required by local, state and federal regulation and national and/or professional standards as applicable.

CIII.1m  Personnel are provided with identification badges or are identified as working for the organization.
D: A review of a randomized sample of written contracts for the provision of care, services and/or products validates adherence to CDI.2, a, b.

I: Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CDI.2a)

Note: The Medicare Certified home health agency must comply with CFR 484.14, 484.14(f, h), 484.36(d). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56, 418.56(b, c, d, e), 418.80). See Appendix IH for a full text of the regulations and a crosswalk.
### CIII.2

**CIII.2** Formal written contracts, executed by the primary organization with other professionals and entities for the provision of care, services, and products to clients of the primary organization, detail specific responsibilities of the parties involved.

**CIII.2a** Written service contracts with individuals and/or other entities are signed and dated by authorized principals of each party and are reviewed annually.

**CIII.2b** The executed document stipulates the terms of the contract which include:

1. Specific services/products to be provided
2. Contractor is required to adhere to applicable primary organization’s policies and procedures
3. Assurance by the contractor of the education, training, qualifications and identification of personnel designated to provide care, services, and products
4. Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable
5. Procedures for the documentation and submission of documented notes that verify the provision of services/products in accordance with the written service contract
6. Procedures for the submission of bills and related information and reimbursement for care, services and products provided
7. Effective dates of the contract including terms of renewal and/or termination
CDI.3

D: Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CDI.3a)

I: The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CDI.3b)

D: Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CDI.3c)

D: The organization has a current operating budget and capital expenditure plan. (CDI.3d)

D: Financial, statistical and productivity reports are used to facilitate oversight of the organization’s operations. (CDI.3e)

I: The chief financial manager describes the use of financial, statistical or productivity reports. (CDI.3e)

I: The chief financial manager validates the adequacy of insurance coverage. (CDI.3f)

D: Review of annual financial review validates that the review was conducted by an organization external to the organization within the most recent twelve month period. (CDI.3g)

Note: The Medicare Certified home health agency must comply with CFR 484.14(l). See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.52, 418.56(d). See Appendix IH for a full text of the regulations and a crosswalk.
CIII.3 The organization's sources of financial support are managed and monitored on an ongoing basis to ensure the availability of adequate funding.

CIII.3a Financial policies and procedures govern the fiscal activities of the organization.

CIII.3b The chief financial manager has the appropriate qualifications, credentials and expertise to oversee, manage, and direct the fiscal operations of the organization.

CIII.3c Major participants in developing and monitoring the budgetary process include the governing body, the chief executive, the chief financial manager, program directors and other designated staff as appropriate.

CIII.3d The operating budget and operating capital expenditure plan is developed using methodologies commensurate with the scope and complexity of the organization's services, programs, and products and is used to forecast financial and operating successes and challenges.

CIII.3e Financial management tools are used to provide operational feedback to administrative and management personnel, financial committees and the governing body.

CIII.3f Adequate insurance coverage is maintained.

CIII.3g An annual external review is required and conducted.
**LEGEND:**

D - DOCUMENTATION  
I - INTERVIEW  
O - OBSERVATION  
S - SURVEY

### CIII.4

| D: | Financial reports detail information used to measure operational performance. (CIII.4a, b) |
| I: | The chief financial manager or other designated party describes the effectiveness of the financial management information systems, the types of reports generated and their use, and internal financial controls (CIII.4a, b, c) |
| D: | Organizational financial procedures used for internal control may include segregation of duties, reconciliation of control accounts, approval levels for disbursements and adjustments, collection of accounts receivable, budgeting, receipt of funds, disbursement of funds, cash and asset account reconciliation and cash management. (CIII.4c) |
| I: | Financial/billing staff confirms timely billing procedures, ongoing monitoring of accounts receivable, implementation of collection efforts as appropriate, and adherence to accounts receivable guidelines. (CIII.4d) |
| D: | Financial reports include payroll and vendor disbursements in accordance with CIII.4e. |

*Note:* The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.
CIIL4 A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to all levels within the organization.

CIIL4a The financial reporting system produces detailed data regarding actual transactions specific to care, services and products provided by each program including site/location activity.

CIIL4b Periodic financial statements contain key indicators and show a reasonable match between revenue and expense line items.

CIIL4c Internal financial controls are in effect.

1) Internal audit procedures and annual review of budget are conducted.
2) Adherence to organizational financial policies and procedures is monitored.

CIIL4d Reimbursable services are billed on a timely basis in accordance with designated fee structures and are monitored, tracked and aged.

CIIL4e Payroll and vendor disbursements are recorded and processed in a structured and timely manner.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.5

D: Applicable statements indicating compliance with OSHA, CDC, ADA, are available and may include:

1) Fire drill and health inspection reports indicate compliance.
2) Certificates of occupancy are posted in accordance with local requirements.
3) Fire and emergency exits clearly detail areas of entrance and egress.
4) Hazardous area access is controlled.
5) Hazardous chemicals and solutions are properly labeled and kept in locked storage.
6) Adequate space and privacy is provided to employees and clients receiving services.
7) Facilities are barrier free and/or special arrangements are made to provide access as indicated and necessary.
8) Safety and security procedures for employees are implemented as necessary.
(CIII.5a)

O: Tour of facility validates compliance with OSHA, CDC, and ADA guidelines and applicable local requirements. (CIII.5a)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c), 418.100(c). See Appendix IH for a full text of the regulations and a crosswalk.
CIII.5 Physical facilities are adequate to support the operations.

CIII.5a Physical facilities meet the OSHA (Federal/State), CDC, ADA and/or State or Local regulations for environmental protection and safety of employees and recipients of service.
CIII.6

**D&I:** MIS manager or other designated party explains and demonstrates how data are collected, processed and secured on and off site. (CIII.6a)

**I:** Management describe how information system is used to ensure organizational accountability. (CIII.6)
CIII.6  A management information system is utilized to ensure accountability at all levels of the organization.

CIII.6a A manual or automated system utilizes established standards and defined data elements for the collection and processing of information.
THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY
I: Management and staff describe the planning process. (CIV.1a)

I&O&D: The assessment of the strengths, weaknesses, opportunities and threats may include the following components:

1) Assess and analyze service area demographics.
2) Maintain current knowledge of organization’s market penetration.
3) Identify new and/or changing consumer and community needs.
4) Collect data and information for analysis.
5) Garner input from all levels of staff.
6) Determine organizational priorities.
(CIV.1b)

I: The CEO and/or governing body representative describes the long term vision and goals for the organization. (CIV.1b)
CIV.1 Strategic planning reflects the organizational mission and includes a comprehensive evaluation of both internal and external environments.

CIV.1a Current budgetary, business and marketing activities are integrated into the process.

CIV.1b An assessment of the organization's strengths, weaknesses, opportunities and threats is conducted on a periodic basis.
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIV.2

D: The organization provides evidence that a current annual evaluation was conducted timely and in accordance with its organizational policies and process. (CIV.2a)

D: The annual evaluation report validates the inclusion of service/product, risk management, human resources and financial and operational components in the evaluation process. (CIV.2b)

I: Administrative/management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D&I: Minutes and interview confirm that the annual evaluation report was presented to the appropriate advisory and governing bodies. (CIV.2d)

Note: The Medicare Certified home health agency must comply with CFR 484.16, 484.16(a), 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a crosswalk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66. See Appendix I H for a full text of the regulations and a crosswalk.
CIV. 2  An Annual evaluation of the organization provides the basis for future planning.

CIV.2a  Organizational policies drive the process for the annual program evaluation by an authorized group and identify the components to be evaluated.

CIV.2b  The complexity of the organization and the scope of care, services, and products provided define the parameters for data collection and utilization and includes service/product, risk management, human resources and financial data.

CIV.2c  Variances from usual and expected patterns of performance are analyzed and explained.

CIV.2d  The Annual Evaluation Report is presented to advisory and governing bodies as appropriate.

CIV.2e  The Annual Evaluation Report is retained as an administrative record.
PHARMACY

STANDARDS OF EXCELLENCE
# TABLE OF CONTENTS

**INTRODUCTION** .................................................................................. iii

<table>
<thead>
<tr>
<th>PRINCIPLE</th>
<th>DESCRIPTION</th>
<th>PAGE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHARMACY I</td>
<td>STRUCTURE &amp; FUNCTION</td>
<td></td>
</tr>
<tr>
<td>DL.1</td>
<td>Statement of Pharmacy Scope of Products/Services</td>
<td>2</td>
</tr>
<tr>
<td>DL.2</td>
<td>Organizational Structure &amp; Functional Mechanisms</td>
<td>3 - 4</td>
</tr>
<tr>
<td></td>
<td>Legal Authority, Legal Documents, Annual Disclosure, Advisory Group</td>
<td></td>
</tr>
<tr>
<td>DL.3</td>
<td>Intra-Organizational Relationships</td>
<td>5</td>
</tr>
<tr>
<td>DL.4</td>
<td>Pharmacy Program Director</td>
<td>6</td>
</tr>
<tr>
<td>DL.5</td>
<td>Pharmacy Specific Policies &amp; Procedures</td>
<td>7 - 8</td>
</tr>
<tr>
<td>DL.6</td>
<td>Ethical Issues</td>
<td>9</td>
</tr>
<tr>
<td>DL.7</td>
<td>Student Education/Research</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PHARMACY II</th>
<th>QUALITY OF SERVICES &amp; PRODUCTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DII.1</td>
<td>Public Disclosure, Client Rights, Ethical Standards</td>
<td>12</td>
</tr>
<tr>
<td>DII.2</td>
<td>Services Provided</td>
<td>13 - 14</td>
</tr>
<tr>
<td>DII.3</td>
<td>Emergency Preparedness &amp; Response</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>24 hours per day/7 days per week accessibility</td>
<td></td>
</tr>
<tr>
<td>DII.4</td>
<td>Access to Services/Inter &amp; Intra-Organization Coordination</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Admission, Coordination, Collaboration</td>
<td></td>
</tr>
<tr>
<td>DII.5</td>
<td>Assessment, Plan of Care, Verbal Orders</td>
<td>17 - 18</td>
</tr>
<tr>
<td></td>
<td>Client/Medication Assessment, Dispensing, Plan of Care, Education</td>
<td></td>
</tr>
<tr>
<td>DII.6</td>
<td>Client Records</td>
<td>19 - 20</td>
</tr>
<tr>
<td>DII.7</td>
<td>Effectiveness of Services</td>
<td>21</td>
</tr>
<tr>
<td>DII.8</td>
<td>Health &amp; Wellbeing of Employees &amp; Clients</td>
<td>22 - 23</td>
</tr>
<tr>
<td>DII.9</td>
<td>Complaints</td>
<td>24</td>
</tr>
</tbody>
</table>
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>PRINCIPLE</th>
<th>DESCRIPTION</th>
<th>PAGE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHARMACY III</td>
<td>HUMAN, FINANCIAL, PHYSICAL RESOURCES</td>
<td>25</td>
</tr>
<tr>
<td>DIII.1</td>
<td>Human Resources Support Workload Demand</td>
<td>26 - 27</td>
</tr>
<tr>
<td></td>
<td>Staffing Guidelines, Orientation, Competencies,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supervision,</td>
<td></td>
</tr>
<tr>
<td>DIII.2</td>
<td>Staffing Contracts</td>
<td>28</td>
</tr>
<tr>
<td>DIII.3</td>
<td>Financial Resources</td>
<td>29</td>
</tr>
<tr>
<td>DIII.4</td>
<td>Physical Facilities</td>
<td>30 - 31</td>
</tr>
<tr>
<td>DIII.5</td>
<td>Information Systems</td>
<td>32</td>
</tr>
<tr>
<td>PHARMACY IV</td>
<td>LONG TERM VIABILITY</td>
<td>33</td>
</tr>
<tr>
<td>DIV.1</td>
<td>Strategic/Operational Planning</td>
<td>34</td>
</tr>
<tr>
<td>DIV.2</td>
<td>Annual Evaluation</td>
<td>35</td>
</tr>
<tr>
<td>DIV.3</td>
<td>Innovations</td>
<td>36</td>
</tr>
</tbody>
</table>
INTRODUCTION TO CHAP PHARMACY STANDARDS

In keeping with its goal of elevating the quality of all community health care in the United States, the Community Health Accreditation Program, Inc. (CHAP) continually reviews and revises the “Standards of Excellence” to ensure currency with and relevance to the community health care industry. The service-specific Pharmacy Standards 2004 Edition are designed to:

- Establish standards of excellence for all types of Pharmacy services (Open Door, Long Term Care, Mail-Order, Internet, Specialty, Compounding, Infusion)
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of Pharmacy clients
- Strengthen the long-term viability of all types of Pharmacy organizations
- Advance the recognition of the Pharmacy organization as an integral component of the national health care delivery system

The re-engineered Pharmacy Standards of Excellence, 2004 Edition, address the scope, complexity and challenges of providing comprehensive Pharmacy services in a variety of community-based settings. When used in conjunction with the CORE Standards, 2004 Edition, compliance is ensured with:

- Pharmacy regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

CHAP standards incorporate most current professional, clinical, industry and regulatory standards and/or requirements.

Underlying Principles

Four key principles form the framework for the revised standards:

I. Structure and Function  III. Resources
II. Quality  IV. Long Term Viability

The four key “Underlying Principles” (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content. The four key underlying principles are used consistently throughout the CHAP accreditation documentation process in the Standards, Self-Study, Workbooks and Site Visit Reports.
UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION AND PURPOSE.

A. Statement of Pharmacy Scope of Products/Services
B. Organizational Structure And Functional Mechanisms
C. Intra-Organizational Relationships
D. Pharmacy Program Director
E. Pharmacy Specific Policies and Procedures
F. Ethical Issues
G. Student Education/Research

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

A. Public Disclosure, Client Rights, Ethical Standards
B. Services Provided
C. Emergency Preparedness & Response
D. Access to Services/Inter & Intra Organization Coordination
E. Assessment, Plan of Care, Verbal Orders
F. Client Records
G. Effectiveness of Services
H. Health & Wellbeing of Employees & Clients
I. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

A. Human Resources Support Workload Demand
B. Staffing Contracts
C. Financial Resources
D. Physical Facilities
E. Information Systems

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic/Operational Planning
B. Annual Evaluation of the Pharmacy Operations and Structure
C. Innovations
As you study and apply these standards to your own organization, give consideration to the following "THEMES" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element - Additional statements that provide more definition of selected elements.

Examples
Standard:.....HMEI.1
Criterion:.............HMEI.1a
Element:...................1)
Sub element:...................(a) (not all standards have sub-elements)

Main Sources of Evidence
D = Documents
I = Interviews
O = Observations
S = Surveys

Substantiation of Findings
Clarification
Verification
Quantification

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.
The Site Visit Report

The Site Visit Report is a written legal document that states the level of compliance by the Pharmacy organization with both the CORE and Pharmacy Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

- **Commendation:** A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.

- **Required Action:** A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.

- **Recommendation:** A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.
THE PHARMACY ORGANIZATION'S STRUCTURE CONSISTENTLY SUPPORTS A CONSUMER ORIENTED MISSION AND PURPOSE
PHARMACY

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.1

D: A printed definition of the organization's scope of products and services is available. (DI.1)

D: Governing body minutes document actions taken on the scope of products and services statement:
   (a) Review and approval within the past twelve months.
   (b) Revisions and updates as applicable. (DI.a)

I: Management and staff describe the process for making scope of products and services statement available upon request. (DI.1b)
A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.

The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.

The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.
D: Required County/State/Federal licenses, authority documents, and Medicare/Medicaid/reimbursement certification (if applicable) are current as required. (DL.2a)

Note: County/State specific licenses may include Sellers Permit, Occupational License, etc.

D: Review of recent findings of other reviewing bodies confirm compliance. (DL.2a)

D: The disclosure statement is current, signed and dated by the chief executive and on file. (DL.2b)

D: Minutes or other formal governing body documents reflect that the governing body authorized an advisory committee. (DL.2c)

Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.

D: Membership in the advisory committee includes a physician, a pharmacist, a registered nurse and at least one community representative. (DL.2c)

D: Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DL.2c)
DI.2 The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.

DI.2a The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.

1) State Board of Pharmacy License
2) Business License
3) DEA Narcotic License
4) d/b/a, Trade Name registration, if applicable
5) Tax ID number
6) Medicare & Medicaid provider numbers, where applicable
7) Specific county and state required authorities

DI.2b The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.

1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization
2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more
3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above
4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility
5) Names and addresses of officers, directors or partners
6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on the part of any person(s) or organization(s) in (1), (2) or (3) above and/or, on the part of any managing employee of the organization
7) The dates of any changes in ownership or control during the previous twelve (12) months
8) The dates of anticipated changes of ownership or control in the next twelve (12) months

DI.2c An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.

1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.
2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee
3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities
4) The Advisory Committee meets at least once annually.
Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)
DI.2d Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program.
DI.3

D: A current organizational chart is available and clearly delineates the lines of authority and accountability for all organizational positions. (DL.3a)

I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (DL3a,3b)
DI.3 Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.

DI.3a A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.

DI.3b The complexity of the Pharmacy organization’s administrative structure is appropriate for efficient delivery of product and service.
DI.4

D: Pharmacy Program Director's resume, diploma, reference checks and current professional license verify compliance with requirements for the position. (DI.4a, DI.4b)

Note: The Pharmacy Program Director may be a regional position in multi-state organizations. In that instance, the Program Director would have a current active Pharmacist license in a state. The Pharmacist in Charge at the specific site will have an active Pharmacist license in that state. The Pharmacy Program Director and the Pharmacist in Charge may be the same or separate position in the organization.

I: Pharmacy Program Director demonstrates knowledge of local, state and federal pharmacy regulations. (DI.4b)

D: The Pharmacy Program Director's job description and/or policies include responsibilities as specified in elements 1-11, or the responsibilities are clearly delegated to other specific positions. (DI.4c)

I & O: The Pharmacy Program Director demonstrates understanding of his/her role. (DI.4c)

D: Written policy and procedure defines assignment of administrative responsibilities in the absence of the Pharmacy Program Director. (DI.4d)

I: Designated alternate to the Director understands his/her role and describes experiences specific to the alternate roles. (DI.4d)

Note: DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.
Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.

The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.

A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.

The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:

1. Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided.
2. Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.
3. Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained.
4. Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice.
5. Assuring adequate and appropriate staffing, including recruitment, orientation, inservice education and completion of annual performance appraisal.
6. Coordinating with other program areas and managers as appropriate, consistent with organizational structure.
7. Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services.
8. Assuring Drug Control system consistent with policies and regulatory requirements.
9. Assuring Drug Dispensing system consistent with policies and regulatory requirements.
10. Assuring appropriate pharmacy supervision at all times.
11. Assuring safe and appropriate service policies are developed and implemented.

A qualified individual is designated in writing to act in the absence of the Pharmacy Director.
PHARMACY

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.5

D: Policies reflect the current practice, professional standards of Service, and scope of service. (DI.5a)

D: Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)

D: Pharmacy operational policies and procedures at a minimum address items 1–25. (DI.5c)

D: Policy is available and includes temperature, light and security. (DI.5c.1)

D: Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)
DI.5 Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.

DI.5a Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.

DI.5b Pharmacy Program administrative policies and procedures include:

1) Regulatory Compliance
2) Capital Short-fall Contingency Plan
3) Pharmacy Reference Materials
4) Annual Evaluation

DI.5c Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:

1) Storage of final pharmaceutical products
2) First dose new drug administration
3) Handling investigational drugs
4) Client/caregiver instruction
5) Timely assessment of client eligibility and provision of service
6) Notification of referral source if client does not meet admission criteria
7) Delivery of services/products, as applicable
8) Contents, dispensing and maintenance of infusion emergency kits
9) Acquisition, storage, disposition & dispensing of controlled substances
10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable
11) Client identification confirmation
12) Availability of latex-free supplies
13) Prescription labeling
14) Materials/Inventory Management
15) Equipment cleaning, testing and tracking
16) After Hours Coverage
17) Dispensing Records
18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility
19) Preparation of injectables from sterile solutions
20) Preparation of injectables from non-sterile powders
21) Preparation of respiratory drugs from non-sterile powders
22) Clinical competency testing
23) Competency testing of sterile product preparation
24) Medication Error
25) Recall
PHARMACY

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DL.5 cont'd

D: Pharmacy clinical policies and procedures at a minimum address items 1–6. (DL.5d)

D: Pharmacy quality improvement policies and procedures at a minimum address items 1–4. (DL.5e)

D: Written policy is available for first dose drug. (DL.5f)
Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:

1) Client Assessment
2) Medication Assessment
3) Drug Profile Review
4) Care Planning, as appropriate
5) Development of a comprehensive care plan
6) Clinical monitoring

Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:

1) Performance Improvement Plan
2) Structure and routine maintenance of compounding areas
3) Maintenance of Laminar Flow Hood
4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals

Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.
**LEGEND:**

D - DOCUMENTATION  
I - INTERVIEW  
O - OBSERVATION  
S - SURVEY

**DL.6**

**D:**  Meeting minutes document discussions of and actions taken by the group, as applicable. (DL.6a)

**I & O:**  Staff demonstrates knowledgeable of and compliance with reimbursement and regulatory guidelines. (DL.6b)
The Pharmacy Organization’s business and clinical activities are conducted according to ethical standards.

A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization. The issues include but are not limited to:

1) Care delivery issues
2) Product and service related issues
3) Billing and collecting issues
4) Medical necessity authorization issues
5) Statistical data trending and tracking issues

Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.
DI.7

I: Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigative studies. (DL.7a)

D: Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DL.7b)

D & I: Documents and interviews validate that current research initiatives exist as applicable. (DL.7c)

D & I: Pharmacy employees publish research findings as applicable. (DL.7d)
### PHARMACY

#### DI.7

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI.7</td>
<td>The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.</td>
</tr>
</tbody>
</table>

#### DI.7a

A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.

#### DI.7b

Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution.

#### DI.7c

The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.

#### DI.7d

The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.
THE PHARMACY ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY PRODUCTS AND SERVICES
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.1

D:  Current Public Disclosure policy includes the element of DII.1a, if applicable, in addition to the elements of CII.1a. (DII.1a)

D:  The Client Bill of Rights statement and/or other admission documents includes elements of DII.1b in addition to the elements of CII.1b. (DII.1b)

D:  Record review confirms that the Client Bill of Rights is signed by the client or client representative and is filed in the record. (DII.1c)

O:  Observation of the open door pharmacy validates that the Client Bill of Rights is posted in a public area. (DII.1d)

D:  Record review validates that pharmacy products and services are provided to clients consistent with the organization’s stated scope of service. (DII.1e)
DII.1 The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.

DII.1a The written public disclosure policy makes the Annual Report for C Corporations, if applicable, available to the public on request.

DII.1b A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:

1) Services and products being provided
2) Organization’s ownership and control
3) Names and qualifications of individuals providing products and services

And the right to:

4) Participate in one’s own care
5) Continuity of products and services
6) Education about the products and services to be provided
7) Refuse part or all of the products and services to be provided
8) Receive products and services in a timely manner and in accordance with organizational policy
9) Be referred to another organization
10) Be free from abuse or exploitation of any kind
11) Receive information, both verbal and written, in an understandable format.

DII.1c The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.

DII.1d For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.

DII.1e The Pharmacy organization’s products and services are provided in accordance with the organization’s scope of services.

1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization’s scope of services.
2) Staff at all levels are knowledgeable about and support the Pharmacy organization’s mission and scope of services.
DII.2

<table>
<thead>
<tr>
<th>I &amp; O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a.</th>
</tr>
</thead>
<tbody>
<tr>
<td>D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)</td>
</tr>
<tr>
<td>I &amp; O: Interviews and direct observation of staff in practice confirms staff understanding and fulfillment of responsibilities. (DII.2b)</td>
</tr>
<tr>
<td>D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)</td>
</tr>
</tbody>
</table>
PHARMACY

DIL.2 Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.

DIL.2a Pharmacy services include but are not limited to:

1) Interpretation and evaluation of the prescription order
2) Drug product selection, compounding, dispensing, storage
3) Distribution of drugs and devices
4) Advising the prescriber and other health care professionals, the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.

DIL.2b Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.

1) Professional pharmacy service is provided by a registered pharmacist and include:
   (a) Overseeing the drug control system including:
       1) Receipt of prescription drugs and prescription orders
       2) Storage of medications
       3) Packaging of medications
       4) Preparation and dispensing of prescriptions
       5) Labeling
       6) Preparation of prescriptions for delivery
   (b) Instruction/counseling clients and caregivers regarding specific drug therapy including possible adverse reactions and/or interactions
   (c) Providing information regarding the safe and appropriate use of medications to other health care professional
   (d) Identifying appropriate outcomes of drug therapy
   (e) Consulting on drug therapy and coordinating with other health care professionals
   (f) Monitoring and documenting ongoing drug therapy including the assessment of:
       1) The therapeutic appropriateness of the choice of drug(s)
       2) Therapeutic duplication in the client's drug routine
       3) Appropriateness of the dose, frequency and route of administration
       4) Adherence to drug regimen
       5) Potential drug, food or diagnostic test interactions of disease limitations to drug use
       6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects
       7) Preparing and maintaining clinical records
   (g) Prescribing activities consistent with state/federal regulations.

2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.
DII.2 cont'd.

I: Procedures for ensuring availability of drugs, supplies and equipment are described. (DII.2c)

I: Job descriptions and/or policies include the indicated delivery personnel responsibilities (DII.2d)

I & O: Interviews and direct observation of delivery services during home visits confirm staff understanding and fulfillment of responsibilities. (DII.2d)

I: Clients relate satisfaction with delivery services. (DII.2d)

I: Procedures for ensuring availability of drugs, supplies and infusion devices when not available from the organization are described. (DII.2e, DII.2f)
The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.

Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:

1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites.
2) Timely delivery of pharmaceuticals and supplies
3) Record keeping
4) Setting up equipment in client homes, if applicable

The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.

The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.
D II.3

I: Staff describe how necessary services (pharmacy and delivery) are made available to clients at all times (on-call practices). (DII.3a)

D: Review of documents (complaint log, client satisfaction survey, on-call logs) validate that response times are consistent with policies and meet client needs. (DII.3a)

D & I: An on-call plan is available, and staff describe the on-call plan. (DII.3b)

O: Testing of the on-call plan validates that the organization is in compliance with its on-call coverage plan and policy. (DII.3b)

I: Client/family describes service availability after hours. (DII.3c)

D: Written contingency plan protocols are available and include items 1–3. (DII.3d)
DII.3 Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.

DII.3a The Pharmacy Organization is accessible and responsive to the needs of clients during normal work hours and after hours which includes:

1) Timely telephone response
2) Timely on-site response, if indicated
3) Product and service delivery prior to scheduled use

DII.3b There is a plan for on-call coverage for after hours, weekends and holidays.

DII.3c Clients are informed of the process for accessing service during normal work hours and after hours.

DII.3d Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:

1) Disaster preparedness
2) Inclement weather events
3) Unexpected critical staffing deficits
DII.4

D: Written policy identifies admission criteria and referral process when the organization does not provide the needed product or service. (DII.4a)

D: Policies and procedures define the responsibilities of the pharmacists, and record review confirms documentation by the pharmacist. (DII.4b)

O: Observation validates assumption/fulfillment of responsibilities. (DII.4b)

D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)

D: Review of records confirms that care coordination activities are performed. (DII.4c, DII.4d)

\[\text{Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4).}\]

D: Client records document interdisciplinary coordination as appropriate. (DII.4e)

I & O: Pharmacists indicate how drug profile information is made accessible to other appropriate professionals, the mechanisms for coordination, the procedures for coordinating delivery of medications, equipment and supplies and that that they are delivered and available as appropriate. (DII.4e)
The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.

DII.4a Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.

DII.4b A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.

DII.4c Care is coordinated for each client by the pharmacist and includes at a minimum:

1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client
2) Timely documentation of the coordination of care activities
3) Involvement of the client/client representative when indicated

DII.4d For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:

1) Initial assessment of the client, family and, if applicable, the home environment
2) Development of a plan of care
3) Determination of expected outcomes
4) Appropriate referral and follow up
5) Implementation of the care plan
6) Ongoing evaluation
7) Plan of termination of care

DII.4e The pharmacist works collaboratively with other health care professionals to assure coordination of care.

1) The client drug profile information is available to professionals participating in the care of the client:
   a) at a minimum, during operating hours for all pharmacies
   b) at all times, including after hours for infusion pharmacies

2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.
DII.5

D: Client assessment policies and record review validate the inclusion of specified items for all pharmacies. (DII.5a)

D: Client assessment policies and record review validate the inclusion of specified items in DII.5a and DII.5b for infusion and long term care pharmacies. (DII.5b)

D: Medication assessment policy and record review validate the inclusion of elements 1-6. (DII.5c)

D, I & O: Interview, observation and record review confirm that client assessments and medication assessments are conducted prior to dispensing. (DII.5a, DII.5b, DII.5c)

D: Policies establish mechanisms for obtaining written physician verification of and approval for verbal orders. (DII.5d)

D: Record review documents that required prescriptions were received prior to dispensing medications. (DII.5d)

D: Record review documents that verbal orders are taken and signed by the Pharmacist prior to filling orders. (DII.5d)
The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.

**DIL.5a** An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Name, address, telephone number, gender, age/date of birth of client
2) Allergies/sensitivities of client
3) Medication Order
4) Physician name, telephone number

**DIL.5b** For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DIL.5a plus the following additional components as appropriate:

1) Chief Complaint/Medical history/Diagnosis
2) Height and weight of client
3) Client Infection, Sensitivities obtained as available
4) Significant Lab Results

**DIL.5c** A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Potential drug interaction
2) Potential for poly-pharmacy
3) Appropriate dose and frequency
4) Appropriate time of administration
5) Appropriate route and method of administration
6) Appropriate infusion device of administration, if applicable

**DIL.5d** Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:

1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication
2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order
D: Written policy is available and includes elements 1-11. (DII.5e)
D: Drug labels include the indicated items. (DII.5e)
D: Plans of care are available for each client and include items 1-6. (DII.5f)

Note: Review by physician may include review of orders, copies of plans of care mailed/faxed to physician. (DII.5f.6)

D: Written policy and procedure define the process for confirming client identification. (DII.5g)
I & O: Pharmacy and delivery staff explain the process for confirming client identification prior to dispensing. (DII.5g)
D: Policies and procedures with specifications detailed are available for emergencies for pharmacy infusion services. (DII.5h)
I: Staff are familiar with emergency procedures and provide examples of their appropriate use. (DII.5h)
D: Drug information and instructional materials are prepared for all types of products and services provided. (DII.5i)
D: Review of documents validates that the client or caregiver was instructed in self-administration of therapy when self-administration was indicated. (DII.5j)
D: Client training/education is documented. (DII.5i, DII.5j)
I & O: Clients understand their regimes. (DII.5i, DII.5j)
DII.5e All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:

1) Name, address and telephone number of the pharmacy
2) Date the prescription was dispensed
3) Expiration date of the medication
4) Pharmacy’s prescription number
5) Client’s full name
6) Name of the drug, brand, strength, if applicable, and the amount dispensed
7) Directions for use
8) Prescriber’s name
9) Other pertinent information or cautionary labels
10) Rate, route and method of administration
11) For IV mixture drugs, rate of administration and expiration date of the fluid

DII.5f A comprehensive plan of care is developed by infusion pharmacies which includes:

1) Establishment of Therapy Specific Goals
2) Determination of Expected Outcomes
3) Determination of Educational Needs
4) Establishment of Monitoring Plan
5) Determination of Achievement of Goals/Outcomes
6) Periodic Review by Prescribing Physician

DII.5g Client identification is confirmed prior to dispensing.

DII.5h For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client’s home, where appropriate.

DII.5i Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.

DII.5j Client training/education in self-administration is provided upon initiation of therapy, as applicable.
D: Client records document that appropriate clinical services were provided to clients. (DII.6a)

D: Client records are current and include elements 1-4. (DII.6a)

D: Client records document adherence to all clinical written policies and procedures. (DII.6a)

D: Client drug profiles are current and include items 1-1. (DII.6a.1)

D: Pharmacy dispensing records include items 2.a-k. (DII.6a.2)

D: Records document adherence to first dose policy for new drug therapies. (DII.6a.2)

D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3. (DII.6a.3)

*Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)*

*Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature initials on the label, on the compounding sheet, etc. (DII.6a.3d)*

D: Narcotic records include items specified. (DII.6a.4)

I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)
DII.6 Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.

DII.6a Adequate and appropriate pharmacy records are maintained:

1) Drug profiles are maintained for all clients and include the following information:
   a. Name, gender, birth date and weight (when appropriate)
   b. Address and client identification
   c. Allergies or sensitivities
   d. Diagnosis
   e. Current drug regimen
   f. Dosages
   g. Relevant clinical information regarding drug therapy
   h. Physician’s name

2) Dispensing records are maintained for pharmaceuticals which include:
   a. Client’s identification, name and address
   b. Name of medication
   c. Strength and dosage form
   d. Quantity dispensed
   e. Physicians’ name
   f. Dispensing pharmacist/technician identification
   g. Prescription number
   h. Date dispensed
   i. Directions for use
   j. Expiration date
   k. Number of refills authorized

3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:
   a. Lot number(s) of drugs
   b. Date of the addition(s) to intravenous admixture drugs
   c. Special compounding instructions as applicable
   d. Documentation of verification procedures

4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:
   a. A controlled substance inventory is performed in compliance with state or federal regulation.
   b. The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals
   c. The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.
DII.6 cont'd.

D: Policy is current and describes signature authentication. (DII.6b)

I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)

O: Pharmacy staff protect data consistent with policy and state law. (DII.6b)

I & O: A back-up and storage system is in place. (DII.6b)
DII.6b Automated clinical record systems ensure consistent and ongoing protection of data.

1) Written policy describes signature authentication in accordance with individual state law
2) Safeguards prevent unauthorized access to inputted information
3) Individual and protected access codes are assigned to individuals designated to perform data entry
4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization
5) The computer's internal clock designates date and time of entries
6) Automated controls prevent a change in entry, allowing only corrections
7) Hardcopies of automated data are retrievable by designated personnel
8) A system for validation of inputted data is in place
9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.
I: The Pharmacy Director describes the performance improvement process for the pharmacy program. (DII.7a)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (DII.7a)

D: The performance improvement program include items specified in DII.7a.

D: The performance improvement plan includes items specified in DII.7b.

D: Evidence exists of monitoring and analysis of findings as specified in DII.7c.

I: Pharmacy Director and staff describe use of findings to identify problems and to improve performance. (DII.7c)

D: Staff orientation and in-service programs validate discussion of improvement program and indicators. (DII.7d)

D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)
DII.7a The Pharmacy Program has a formalized quality improvement program which is designed to:

1) Identify desired outcomes
2) Identify strategic and at-risk activities
3) Establish monitoring parameters for these activities
4) Establish minimal standards or criteria to be met
5) Describe methods used to improve the quality of service and to achieve the desired outcomes.

DII.7b The Pharmacy Program has a written performance improvement plan which includes:

1) Description of specific monitoring and evaluation activities
2) Specification of how results are to be reported and evaluated
3) Identification of appropriate follow-up mechanisms when thresholds are exceeded
4) Delineation of individual responsibilities for each aspect of the program.

DII.7c The Pharmacy Program's performance improvement program includes but is not limited to:

1) Monitoring for medication errors
2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.

DII.7d Staff orientation and in-service programs integrate a focus on quality.

DII.7e The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.
DII.8

D: Written policies exist and include items 1-10. (DII.8a)

D: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)

D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)

D: Policy requires the designated stipulation for the disposal of controlled substances. (DII.8c.1)

D: Records confirm adherence to policy. (DII.8c.1)

D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)

O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2)

Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.

D: Written instructions regarding disposition of hazardous substances in homes are provided to appropriate clients. (DII.8c.3)

I: Staff and client are aware of disposition procedures for hazardous substances, if indicated. (DII.8c.3)

D: Records confirm adherence to policy and regulation. (DII.8c.4)

D: Client instructions regarding preparation of sterile solutions, storage methods, and durations are documented. (DII.8d)

I: Clients preparing sterile solutions at home are able to describe appropriate preparation and storage precautions. (DII.8d)
DII.8 The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.

DII.8a Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:

1) Observation of standard precautions
2) Adequate hand hygiene/hand washing
3) Procedures for preventing exposure to blood borne pathogens
4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances
5) Use of aseptic technique
6) Appropriate use of particulate and/or bacterial filtration
7) Hood decontamination practices
8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs
9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container
10) Proper disposal for hazardous waste products

DII.8b When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.

DII.8c Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.

1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.
2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products
3) Clients are instructed regarding the proper disposal of hazardous products in the home
4) Records are maintained, as required

DII.8d When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:

1) Instructions regarding the preparation of the sterile solution
2) Storage methods
3) Duration and stability of the prepared solution
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.8 cont'd

D: Written infection control and safety policies for equipment/delivery service are available. (DII.8e)

I & O: Staff demonstrate an understanding of infection control procedures and policies. (DII.8f)

D: Policies specify elements 1 – 5 of DII.8f. (DII.8f)

D: Policies specify maintenance, testing, and repair specifications for each type of equipment. (DII.8f)

I & O: Equipment is maintained, tested, and repaired according to manufacturer's recommendations. (DII.8f)

D & O: Review of records and observation of practice confirms adherence to organizational policies and that activities are conducted on a routine basis. (DII.8f)
DII.8e  Infection control and safety control policies are established and implemented for the equipment/delivery service, including:

1) Maintenance, testing and repair of equipment according to manufacturer's guidelines
2) Cleaning and storage of reusable equipment between usage
3) Inspection of equipment prior to delivery.

DII.8f  The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:

1) Routine disinfection and quality testing of direct compounding environment
2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures
3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients
4) Visual inspection of compounding sterile products
5) Media-fill test procedure performed at least annually for each person
DII.9

D: Documentation validates that the complaint process includes elements 1-9. (DII.9a)

D: Review of complaint log validates that complaints have been responded to consistent with the organization’s policy and process. (DII.9a)
DII.9

Client complaints and concerns are responded to and resolved in a timely manner.

DII.9a The complaint process includes:

1) Designation of the individual(s) responsible for responding to the complaint
2) Procedures for responding to complaints
3) Time frame for responding to complaints
4) Assurance that corrective action is taken as appropriate
5) Assurance that client and family rights are protected
6) Follow-up activities
7) Resolution of the complaint
8) Complainant is informed of the outcome
9) Trending of justified complaints
THE PHARMACY ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES, WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION
**DIII.1**

**D:** Staffing assignments are available. (DIII.1a)

**I:** Mechanisms for evaluating workload demands are described. (DIII.1a)

**I:** Mechanisms for employee selection are described. (DIII.1b)

**D:** Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DIII.1b)

**D:** Records include diplomas/transcripts, current licenses and continuing education attendance (if required) for all clinical/professional staff. (DIII.1b.3, 4, 5)

**D:** Documentation of certification or adequate training is available for Pharmacy Technicians and Delivery personnel identifying training provided for all tasks performed by the technician and the Driving personnel. (DIII.1b.6, 8)

**I:** Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)

**I:** Mechanisms for assessing and updating clinical competencies/skills are described. (DIII.1c)

**D:** Documentation of clinical competency/skill assessment at time of hire and annually thereafter is available. (DIII.1c)

**D:** Documentation of clinical competency assessment including elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)

**I:** Mechanism for assessing clinical competency is described by manager and pharmacy personnel. (DIII.1d)
DIII.1 The Pharmacy organization has adequate and appropriate human resources to meet workload demands.

DIII.1a Staffing guidelines are developed and implemented to adequately meet workload demand.

DIII.1b Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:

1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands
2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals
3) Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization
4) Clinical staff maintain and show evidence of current licensure
5) Clinical staff show evidence of continuing education when required
6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws
7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license
8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed
9) Professional & technical personnel show evidence that professional skills are assessed and updated
10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.

DIII.1c Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:

1) At time of hire
2) Annually, thereafter

DIII.1d Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:

1) Written test to verify employee's understanding of the concepts of aseptic technique
2) Observation of employee's aseptic technique
3) Sterility validation testing for all employees who make sterile products
4) Observation of cleaning, testing and calibration of infusion equipment
5) Observation of cleaning, testing and calibration of compounding equipment
An orientation plan is available and includes elements 1-5. (DIII.1e)

There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)

Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g)

Note: In-services may be provided by the organization or other approved entities.

Records show documentation of organization's provision of annual in-service program and pharmacist's attendance at the in-service. (DIII.1h)
The orientation plan addresses at a minimum:

1) Mission statement
2) Organizational Chart
3) Lines of authority and responsibility
4) Job related responsibilities (job description)
5) Human Resources policies/conditions of employment

There is adequate supervision of all pharmacy personnel.

1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.
2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.

Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.

The organization provides a minimum of one medication safety in-service annually.
DIII.2

D: Contracts for Pharmacy services contain all elements in CIII.2a-b, DIII.2a and DIII.2b. (DIII.2b)

D: Contracts for Delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)

I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)
### DIII.2

**Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.**

| DIII.2a | Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIIl.2a-b and, in addition, the following specific responsibilities:
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1) Which organization has the authority to accept and terminate client services</td>
</tr>
<tr>
<td></td>
<td>2) Services provided under contract must be in compliance with professional standards</td>
</tr>
<tr>
<td></td>
<td>3) The manner, in which products and services will be controlled, coordinated and evaluated</td>
</tr>
<tr>
<td></td>
<td>4) Designation of responsibilities for orientation</td>
</tr>
</tbody>
</table>

| DIII.2b | Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIIl.2a-b, DIII.2a and, in addition, include the provisions for:
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1) Who is responsible for teaching the client about pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>2) Assurance that personnel meet the pharmacy program’s educational and training requirements</td>
</tr>
<tr>
<td></td>
<td>3) Maintenance of current licensure and certification where required</td>
</tr>
<tr>
<td></td>
<td>4) On site supervision of pharmacy personnel</td>
</tr>
<tr>
<td></td>
<td>5) Hours when pharmaceutical services are available to the client, including arrangements for services during “off hours”</td>
</tr>
<tr>
<td></td>
<td>6) Time frames for response to new referrals</td>
</tr>
</tbody>
</table>
| | 7) Responsibilities of contractor and contractee, including:
| | (a) Who assesses the need for pharmaceuticals |
| | (b) Who contacts the pharmacy |
| | (c) Who obtains the written physician orders |
| | (d) Who generates drug profiles and to whom they will be made available of those involved with the client’s care |
| | (e) Who maintains records for investigational drugs and controlled substances |
| | (f) Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy |
| | (g) Mechanisms for evaluating the contracted service |

| DIII.2c | Delivery of products and supplies when provided to clients under arrangement are in compliance with CIIl.2a-b, DIII.2a and, in addition, include the provisions for:
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1) Ensuring clean and safe transport of equipment and supplies</td>
</tr>
<tr>
<td></td>
<td>2) Timely delivery of products and supplies</td>
</tr>
<tr>
<td></td>
<td>3) Setting up equipment in client’s homes, where appropriate</td>
</tr>
<tr>
<td></td>
<td>4) Adequately trained delivery personnel</td>
</tr>
<tr>
<td></td>
<td>5) Client education, where appropriate</td>
</tr>
<tr>
<td></td>
<td>6) Appropriate documentation</td>
</tr>
</tbody>
</table>
DIII.3

D: Policies pertaining to cash management and contingency planning are available. (DIII.3a)

I: Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning. (DIII.3a)

D&I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)

D: New Pharmacy product/service plan proposals include specified elements. (DIII.3c)

I: Management team describes examples of recognition of inter-relationship of finance, quality, product and service operations. (DIII.3d)
The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.

| DIII.3a | The organization has a contingency plan and/or policies and procedures to adequately address cash or operating shortfalls that may impact the products and services it provides. |
| DIII.3b | Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work-related injuries. |
| DIII.3c | New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project. |
| DIII.3d | The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization. |
Observation of the physical facility validates that elements 1-7 are in evidence and in conformance with state/federal requirements. (DIII.4a)

Written policies specify elements 1-5. (DIII.4b)

Work surfaces and equipment are cleaned and disinfected in compliance with pharmacy policy. (DIII.4b)

Note: Compounding environment includes walls and floors. (DIII.4b.2)

Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)

Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)

Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications designated in elements 1-3. (DIII.4e)
The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.

The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:

1) Preparation of sterile products for dispensing is within an ISO Class 5 environment
2) Hot and cold running water with sink
3) Walls, ceilings and floors made of non-porous cleanable surfaces
4) Accurate balance and measuring devices
5) Adequate ventilation and lighting
6) Disposable hand drying towels
7) Adequate storage facilities
   (a) Parenteral compounding items stored to maintain integrity of aseptic environment
   (b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.
   (c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/foam

The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:

1) The adequacy of workspace per state regulations
2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected
3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug
4) Certification of laminar flow hood per organizational policy and/or state/federal regulation
5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.

Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.

Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.

There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:

1) Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination
2) Use of laminar flow hoods
3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs

Revised: 3/13/06
D: Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f)

D: Certification reports from the most current three year period are available. (DIII.4f)

I & O: Pharmacy personnel are knowledgeable of and use appropriate techniques when using a hood or cabinet. (DIII.4g).

I&O: Interviews with staff and observation of practice confirms compliance with policies. (DIII.4h, DIII.4i, DIII.4j)

D: Written policies specify elements 1-5. (DIII.4k)

O: Products are shipped in compliance with the pharmacy’s policy. (DIII.4k)

O: Client service areas are private, clean, safe and in compliance with ADA regulations. (DIII.4l)
DIll.4f Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.

DIll.4g Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.

DIll.4h Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.

DIll.4i Injectables prepared from non-sterile powders are:

1) Dissolved in sterile solution for injection
2) Filtered through a 0.2 micron filter.

DIll.4j Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:

1) Dissolved in sterile solution
2) Filtered through a 0.2 micron filter
3) Packaged under ISO 5 environment conditions
4) Periodically end product tested

DIll.4k Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:

1) Assurance of stability and potency of the products being shipped
2) Temperature control
3) Non-exposure to light
4) Non-exposure to contaminants
5) Packaging of medications in a tamper evident manner

DIll.4l The organization’s physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.

1) Space and privacy are adequate for the services being provided
2) Physical facilities and resources permit effective and efficient function of the personnel
3) Provisions are made to accommodate clients and staff with disabilities
D: External databases are available and used for comparison. (DIII.5a)

D: Benchmark reports are available. (DIII.5b)

Note: Organizations may use internal standards, professional standards of practice guidelines, research findings or professional references to determine benchmarks.

Organizations may use multiple sites, divisions and/or professional reference data to benchmark against.
<table>
<thead>
<tr>
<th>DIII.5</th>
<th>An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIII.5a</td>
<td>When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.</td>
</tr>
<tr>
<td>DIII.5b</td>
<td>The organization participates in a benchmarking system.</td>
</tr>
<tr>
<td></td>
<td>1) Benchmark data are consistent with organizationally defined goals and objectives</td>
</tr>
<tr>
<td></td>
<td>2) Benchmark collected data, when available, are measured against data from other organizations</td>
</tr>
</tbody>
</table>
THE PHARMACY ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY
LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.1

D: The pharmacy operational plan is available. (DIV.1a)
D: Governing Body meeting minutes document approval of the
    initial pharmacy operational plan and changes. (DIV.1b)
DIV.1 Operational planning reflects the Pharmacy's mission.

DIV.1a The planning process focuses on performance expectations and is consistent with organizational needs.

DIV.1b The written plan is developed, and the initial plan and changes are approved by the governing body.
D: An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)

I: Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)

I: Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D & I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)

D: The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)
DIV.2  An annual systematic evaluation of major aspects of the Pharmacy Organization’s program and operations provides the basis for future planning.

<table>
<thead>
<tr>
<th>DIV.2a</th>
<th>Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIV.2b</td>
<td>Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.</td>
</tr>
<tr>
<td>DIV.2c</td>
<td>Pricing of products and services is routinely evaluated.</td>
</tr>
<tr>
<td>DIV.2d</td>
<td>Results of the Pharmacy organization’s evaluation findings are integrated into the corporate organization’s report, if applicable.</td>
</tr>
</tbody>
</table>
DIV.3

O: Innovations have been developed and implemented.
   (DIV.3)
DIV.3  The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.

**DIV.3a**  A common and futuristic vision of the organization is established and sustained.

1) A learning environment for all staff is promoted and supported  
2) Staff development is encouraged  
3) Governing body members have expertise specific to the enhancement of the organization's mission

**DIV.3b**  An atmosphere of mutual respect permeates the organization throughout.

1) Interaction between staff, administration and governing body is evident and is facilitated

**DIV.3c**  The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.

**DIV.3d**  The organization actively networks with other providers and provider organizations.
Community Health Accreditation Program, Inc.

Job Description
Site Visitor Per Diem

Position Description:

Under the direction of the Regional Director of Professional Services the Site Visitor plans, organizes, coordinates and conducts community based health care organization accreditation site visits in accordance with assigned activities. Accreditation activities are executed in accordance with CHAP Policies and Procedures governing the accreditation process. The CHAP Site Visitor ensures the protection of the confidentiality of all related site visit information except as otherwise required by law.

Qualifications

- Five (5) years experience in middle to upper management position in a health care field in at least one program or service accredited by the Community Health Accreditation Program, Inc. (CHAP).
- Bachelor’s Degree in a related specialty area required. Master’s Degree preferred.
- Active license to practice in home state, where required by discipline.
- Demonstrates analytical, consultative, conflict resolution, mediation, written and verbal articulation skills with effective critical thinking aptitude.
- Ability to work effectively as part of the accreditation team.
- Successful completion of the CHAP site visitor orientation program which includes: didactic classroom, competency testing and mentored site visit(s).
- Exceptional organizational and time management skills.
- Ability to travel independently.
- Demonstrates excellent interpersonal skills.
- Demonstrates proficiency with computer skills and office applications.
- Requires availability of a minimum of ten site visit days per month

Responsibilities:

1. Represent CHAP in a professional manner Accept assignments
   a. Report availability to CHAP Scheduler in established time-frame
   b. Confirm travel arrangements in a timely manner in relation to when the assignments are made
2. Prepare for assignments to include as appropriate:
   a. Review agency self-study to assist in planning visit
   b. Collaborate with team members
3. Complete site visit requirements and documentation in an organized and timely manner
4. Submit required site visit documentation within required time frame
5. Demonstrate knowledge and application of CHAP accreditation process, Standards of Excellence, State and/or Federal Regulations.
6. Provide clarification, verification and quantification of site visit findings.
7. Participates in scheduled CHAP meetings
8. Performs other functions as assigned
This position involves part time work which will require full time independent travel by air or car or other means. Due to the nature of this job, lifting of materials and equipment of up to 50 pounds is required. Extended periods of sitting/standing are required.

Speaking in fluent English is required as are excellent writing skills for written correspondence. The candidate must be able to hear, see and comprehend written documents to effectively perform this job. Extensive work on a PC and telephone, at a desk, is required.

The physical demands and work environment that have been described is representative of those an employee encounters while performing the essential functions of this position. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions in accordance with the Americans with Disabilities Act.

I have reviewed the above job description and had an opportunity to have my questions answered. I understand and agree to perform all essential functions to the best of my ability.

_________________________  __________________________
Signature                          Date
**Introductory Site Visitor Evaluation**

This evaluation is completed within 90 days of hire. Each Site Visitor is expected to have completed 4-6 site visits by then.

---

**Site Visitor Name:**

**Date(s) of the Site Visit(s):**

The rating scale is as follows:

- 5 = Always
- 4 = Frequently
- 3 = Sometimes
- 2 = Rarely
- 1 = Never
- 0 = Not Applicable/Unable to Assess

<p>| | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demonstrated preparedness to work as a member of team in conducting the site visit.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Demonstrated introductory knowledge of CHAP standards specific to the site visit.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Accurately interpreted and applied State and Federal Regulatory requirements specific to the site visit.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Demonstrated accuracy, appropriateness and objectivity in collecting, clarifying, quantifying, interpreting, and reporting data.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5. Used appropriate decision making processes.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6. Developed relationships with co-team members and agency staff that facilitated the site visit process.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7. Carried out responsibilities related to the site visit in an organized and professional manner</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>8. Demonstrated effective time management skills.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>9. Was a professional role model for CHAP.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>10. Employed effective interpersonal skills when dealing with patients, families, staff, and administrative personnel.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>11. Articulated findings in a clear, succinct and professional manner.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>12. Provided valuable consultation to staff and administrative personnel.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**Strengths:**

---

P:\Human Resources\Performance Management\Introductory Site Visitor Evaluation 11.11.08.doc
Cleared for Independent Site Visits: ☐ Yes ☐ No

Service Director Signature and Date: ____________________

Site Visitor Signature and Date: ______________________
Performance Evaluation For Site Visitors

Performance Evaluation

Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800 Washington, DC 20005

CHAP PERFORMANCE MANAGEMENT AND EMPLOYEE DEVELOPMENT PROGRAM

The primary objective of CHAP's Performance Management Program is to improve future performance - align resources, increase skills, provide support and encouragement, and challenge ourselves to stretch. This program is a tool for both supervisors and employees to periodically develop goals and objectives, identify strengths, recognize achievement, and define training or improvement plans for areas requiring development. The program is designed to communicate performance expectations across the organization and provide opportunity for employees to achieve their goals. This is accomplished through a process that includes the following:

- expected results
- expected behaviors
- individual development planning

Managing Daily Performance (ongoing):
- constructive feedback
- coaching
- recognition
- removing obstacles
- discipline when necessary
- documentation

Performance Summary:
- to be done for the following review periods (first 90 days and annually):
  - documentation by employee and supervisor
  - discuss results and behaviors used to achieve results

PERFORMANCE SUMMARY

Step 1. Each employee prepares a self-assessment by completing an annual Performance Summary document and submits it to his/her supervisor.

Step 2. The manager reviews the self-assessment that the employee submits and then completes an annual Performance Summary document.

Step 3. The employee and manager jointly review performance, ensuring all relevant information is considered. Any agreed upon changes should be made on the Performance Summary, which is the official document.

Step 4. The supervisor submits the Performance Summary to the Chief Operating Officer who will forward to HR.

Step 5. Merit increases, based on performance, economics and company factors, will go into effect once approved by the Chief Operating Officer.

MEASURES

Measures are an important component of performance management. Measures not only provide information, they influence performance. The company has developed performance criteria for all positions to measure employee performance. The company recognizes that how an employee accomplishes tasks is as important as the results. The company has identified the following five competency areas that are critical to our success. Each employee's performance is measured relative to each of these:

- Customer Satisfaction (both internal and external)
- Job Acumen
- Results
- Team Success
- Professional Development (of self and others)

In addition, we have identified management competencies that are paramount to the individual and company's success that will be evaluated. You and your supervisor jointly will set annual goals which will also be evaluated.

SUPPORTING CHAP OBJECTIVES

Each of the five core competencies helps support our overall Company Mission. Additionally, they also support the key objectives that CHAP is focused on which include:

- Quality
- Customer Satisfaction
- Financial Success
- People Success
- Growth
Performance Evaluation For Site Visitors

Type of Review: Choose an item.

<table>
<thead>
<tr>
<th>Employee</th>
<th>Click here to enter text.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
<td>Site Visitor</td>
</tr>
<tr>
<td>Supervisor</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Period of Performance</td>
<td>Starting Date</td>
</tr>
<tr>
<td></td>
<td>Click here to enter a date.</td>
</tr>
</tbody>
</table>

The following rating definitions are to be used when valuating performance in the core competencies. Please carefully read each definition and fairly use the following to complete your assessment.

<table>
<thead>
<tr>
<th>LEVEL OF PERFORMANCE</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceptional: Employee's results and behaviours are extraordinary in all key areas relative to requirements and expectations and in comparison to the results of other top performers. This rating is used as recognition for those who are proactive, take initiative, and have accomplished tasks and/or projects that have significant impact on the organization. The individual has taken responsibility for ensuring that goals were achieved when, otherwise, they may not have been attained. This individual is a role model for others.</td>
<td>E</td>
</tr>
<tr>
<td>Commendable: Frequently exceeds established departmental performance expectations. Often excels in demonstrating the knowledge, skills and abilities that result in the effective performance of the position requirements. This individual regularly takes responsibility for ensuring goals were achieved and continually improves his/her performance and models appropriate behaviors for other team members.</td>
<td>C</td>
</tr>
<tr>
<td>Solid: Employee's results and behaviors consistently meet expectations in all key areas. The individual has reliably contributed to the agency's outcomes and to the overall effectiveness of the branch/department by applying the skills necessary to complete assigned tasks. The individual strives to continually improve his/her own performance and the performance of the team. This individual is a valued member of the organization.</td>
<td>S</td>
</tr>
<tr>
<td>Needs Improvement: Some aspects of the employee's performance, within their ability to influence or control, did not meet requirements and expectations. This rating describes performance that needs improvement and guidance, coaching, and/or corrective action planning in order for the employee to meet or exceed the agency's expectations in the future.</td>
<td>N</td>
</tr>
<tr>
<td>Unacceptable: The individual has demonstrated little or no contribution to team, branch, department and/or organizational goals and has failed to meet assigned tasks. Requires a Performance Improvement Plan w/ 30-60 day plan of correction.</td>
<td>U</td>
</tr>
</tbody>
</table>
SECTION I - OVERALL PERFORMANCE OBJECTIVES & RESULTS - Consider the accomplishments achieved throughout the performance period and document what was accomplished and how well it was accomplished.

<table>
<thead>
<tr>
<th>Customer Satisfaction</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Takes initiative to meet agency needs</td>
<td></td>
</tr>
<tr>
<td>- Responds to internal and external requests in a timely manner</td>
<td></td>
</tr>
<tr>
<td>- Proactively recognizes potential problems and takes action to resolve them</td>
<td></td>
</tr>
<tr>
<td>- Is recognized positively by internal and external customers</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation of Achievement</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Job Acumen</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Performs all essential functions of the job accurately</td>
<td></td>
</tr>
<tr>
<td>- Develops and maintains expert level of knowledge about Standards of Excellence</td>
<td></td>
</tr>
<tr>
<td>- Develops and maintains expert level of knowledge about CMS Conditions of Participation and/or Quality and Supplier standards</td>
<td></td>
</tr>
<tr>
<td>- Interprets and analyzes standards and evidence consistently and accurately</td>
<td></td>
</tr>
<tr>
<td>- Provides applicants and accredited organizations education on performance improvement</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation of Achievement</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Submits required Site Visit documentation within 2 Business days</td>
<td></td>
</tr>
<tr>
<td>- CARES documentation is accurate and complete. Includes a Summary and Accreditation Recommendation and as per documentation guidelines, organization strengths and challenges</td>
<td></td>
</tr>
<tr>
<td>- Site visits are conducted effectively</td>
<td></td>
</tr>
<tr>
<td>- Evidence is fact based and relevant</td>
<td></td>
</tr>
<tr>
<td>- Written documentation is clear and substantiates cited evidence</td>
<td></td>
</tr>
<tr>
<td>- CMS documents are complete and accurate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation of Achievement</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Team Success</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Builds positive relationships and team morale</td>
<td></td>
</tr>
<tr>
<td>- Asks for and offers help</td>
<td></td>
</tr>
<tr>
<td>- Sets a good example and motivates others</td>
<td></td>
</tr>
<tr>
<td>- Coordinates and collaborates with all team members</td>
<td></td>
</tr>
<tr>
<td>- Provides updated license, as required, and consulting detail timely</td>
<td></td>
</tr>
<tr>
<td>- Actively avoids any appearance of Conflict of Interest</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation of Achievement</th>
</tr>
</thead>
</table>
SECTION II - COMPETENCIES AND MANAGEMENT SKILLS - Evaluate the extent to which competencies and/or management skills were demonstrated in achieving desired results.

<table>
<thead>
<tr>
<th>Competencies</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepting Supervision</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Attention to Detail</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Authority and Presence</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Business Acumen</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Clear Written and Verbal Communication</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Conducting Entrance/Exit Conferences</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Dependability</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Development/Mentoring</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Flexibility and Adaptability</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Integrity</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Judgment/Decision Making</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Leadership</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Managing Change</td>
<td>Select Rating</td>
</tr>
</tbody>
</table>

Fill in the number of times the individual received each rating.

<table>
<thead>
<tr>
<th>Exceptional</th>
<th>Commentable</th>
<th>Solid</th>
<th>Needs Improvement</th>
<th>Unacceptable</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION III – GOAL ACCOMPLISHMENT and PROFESSIONAL DEVELOPMENT - Evaluate the extent to which specific annual goals and professional development for the evaluation period were accomplished. Next, set goals and identify areas of professional development for the upcoming year and describe the action plan for meeting those goals and any resources needed to support professional development.

<table>
<thead>
<tr>
<th>GOAL ACCOMPLISHMENTS</th>
<th>Goals For Past Year</th>
<th>Evaluation of Achievement</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Select Rating</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Select Rating</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Select Rating</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOAL DEVELOPMENT</th>
<th>Goals For Upcoming Year</th>
<th>Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION V - EVALUATION & SIGNATURES – Considering accomplishment of objectives set during the performance period and contribution to organizational results, evaluate the overall performance of the individual being reviewed.

<table>
<thead>
<tr>
<th>EVALUATION COMPONENTS</th>
<th>OVERALL EVALUATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Satisfaction</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Job Acumen</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Results</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Team Success</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Professional Development</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Competencies</td>
<td>Select Rating</td>
</tr>
<tr>
<td>Goal Accomplishment</td>
<td>Select Rating</td>
</tr>
</tbody>
</table>

**SIGNATURES**

The original signed and dated Annual Review is to be forwarded by the Supervisor to HR for signatures and then placement in the employee's personnel file.

<table>
<thead>
<tr>
<th>Role</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee: (all reviews)</td>
<td></td>
</tr>
<tr>
<td>Supervisor: (all reviews)</td>
<td></td>
</tr>
<tr>
<td>Chief Operating Officer: (annual review only)</td>
<td></td>
</tr>
<tr>
<td>Human Resources: (annual review only)</td>
<td></td>
</tr>
</tbody>
</table>

Our Mission is to provide leadership for enhancing the health and well being of diverse communities. Thank you for being a part of our team and assisting to further our mission. Your efforts directly impact the success of CHAP!
Accreditation Commission for Health Care, Inc (ACHC)
March 30, 2010

Debbie Anderson
Site Licensing Manager
California Board of Pharmacy
1625 N. Market Blvd.
Suite N219
Sacramento, CA 95834

The Accreditation Commission for Health Care, Inc. (ACHC) would like to request the California Board of Pharmacy to accept ACHC for re-approval as an accrediting organization for pharmacies that compound injectable sterile products. Please consider the following information and attached documents in your decision process:

1. Periodic Inspection – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years:
   I. ACHC accreditation is valid for three years. Each provider must re-apply prior to the expiration of their three year accreditation. Re-accreditation requires a full site survey. Please see attached copy of ACHC policies and procedures, and reference specific section below that addresses re-accreditation requirements:

      C. Accreditation Status Criteria
         Approval of Accreditation
         Full accreditation is awarded to an organization when the overall score and each section score are within a range of 90% or above. Submission of a plan of correction will be required for any standard not fully met. Accreditation is good for 3 years. Effective accreditation dates for new and renewal organizations are determined as follows:
         New organization:
         1. First day following the survey, if the organization passes survey on the first review.
         2. First day after receipt of plan of correction once the plan of correction is approved from deferral status.
         3. First day after the focus survey, if the deferral is cleared upon review.
         Renewal organization:
         1. First day following current accreditation expiration date if the organization passes survey on the first review.
         2. First day following current accreditation expiration once the plan of correction is approved from deferral status.

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:
   a. ACHC grants accreditation based on many components of the survey. The clinical manager for pharmacy services reviews each summary of findings, the scoring grid and the surveyor’s comments after each survey. A decision is made based on all three criteria. Accreditation is granted for
scores of 90% and above; the deferral range is 80% to 89% and denial is determined for scores below 80%.

b. Standard 107A as stated below reflects any state specific criteria that is met or not met by a provider during the survey.

*Standard 107, Criterion A: There are written policies and procedures established and implemented by the organization regarding compliance with all applicable federal, state, and local laws and regulations. The organization also complies with accepted professional standards and practices.*

*Note: Failure to meet this criterion will result in automatic deferral.*

c. Please see attached standards for accreditation for pharmacies.

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

ACHC surveyors for pharmacies are required to meet the following criteria:

a. Maintain a current pharmacist license in one of the 50 states or territories of the United States. Surveyor is required to have a minimum of 5 years managerial experience in the homecare and/or pharmacy market. A PharmD is preferred.

b. Surveyor must complete the initial two day surveyor training and a minimum of two preceptorships, prior to conducting their initial survey.

c. Surveyors must attend an annual full day training session.

d. Surveyors must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards.

e. All surveyors are evaluated annually for their ability to perform surveys in accordance with ACHC policies and procedures.

4. Acceptance by major California payors — Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS)

I. ACHC is recognized by most major payors; example of these payors in California are: Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurnNational California and the California Department of Health.

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.

I. ACHC welcomes feedback from the California Board of Pharmacy on any ACHC accredited organization that is licensed by the Board.

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

I. ACHC will make available to California Board of Pharmacy any provider’s Summary of Findings as requested. In addition the Board can access current accredited provider by visiting our website.
7. Length of time accrediting agency has been in operation.
   I. ACHC is an independent, private, not-for-profit corporation established in 1986.

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.
   I. ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the United States.

Thank you for considering ACHC for re-approval as an accrediting organization for the California Board of Pharmacy in regard to pharmacies that compound injectable sterile drug products. If you have any questions or require additional information please call me at 919-785-1214.

Mary Lou Seufert-Fleming
Regulatory & Governmental Affairs Liaison
Accreditation Commission for Health Care, Inc.
Tel: (919) 785-1214 X249
Fax: (919) 785-3011
www.achc.org
SECTION 100: Business Operations and Administration

Standard 101. The organization is an established entity with legal authority to operate.

Standard 101, Criterion A: There is appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: Legal authority is granted to one individual, members of a limited liability corporation, a board of directors, or a board of health; usually referred to as the governing body, and as allowed in state statutes for the appropriate type and structure of the organization. Whether private or public entity, the individual, or organization will have a copy of the appropriate authorization(s) to conduct business. All required license(s) and or permit(s) must be current and posted in a prominent location accessible to public view in all locations/branches and/or in accordance with appropriate regulations or law.

Evidence: Copy of Articles of Incorporation/Bylaws and all applicable amendments
Copy of all current applicable license(s)/permit(s) for each premise

Standard 101, Criterion B: The organization’s written policy and procedure defines action requirements for request for information and changes in authority, ownership, or management.

Interpretation: The organization’s written policy and procedure describe the required action and timeframes if a request for information is received from a regulatory or accrediting body, or there is a change in ownership, governing body, or management.

Evidence: Written Policies and Procedures
Response to Interviews

Standard 102. The organization’s leadership assumes full legal authority and responsibility for the operation of the organization. Examples of leadership positions may include the owners, governing body, chief executive officer, and other individuals responsible for managing services provided by the organization.

Standard 102, Criterion A: Governing body duties and accountabilities must be clearly defined.

Interpretation: A governing body assumes full legal authority and responsibility for the operation of the organization consistent with acceptable standards of practice. Activities of the governing body may include but are not limited to the following: decision making, appoints a qualified administrator, arranges for professional advice, reviews the annual program evaluation, adopts and periodically reviews written bylaws or equivalent, establishes or approves written policies governing operations, human resource management, quality improvement, community needs planning and oversight of the management and fiscal affairs of the organization.
Policies must be reviewed and revised on an ongoing basis as needed and reviewed/revised as part of the annual evaluation.

Although many governing bodies delegate authority for some of these functions to individual staff members or to an advisory committee, the ultimate responsibility continues to rest with the governing body. In situations where the board of directors serves as the governing body for a large, multi-service organization, board activities will address the overall organization; however, oversight of the organization’s program must be evidenced in some manner such as reports to the board documented in minutes of board meetings.

Evidence: Written Policies and Procedures
Minutes of Board of Directors Meetings
For privately owned organizations whose owners serve as leader/executive, records of organizational decisions including dates and participants
Response to Interviews

Standard 103. The organization has a written policy and procedure which defines conflict of interest and the procedure for disclosure.

Standard 103, Criterion A: The organization’s written policy defines conflict of interest.

Interpretation: The organization’s policy defines conflict of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and clients/patients. The policy must include the required conduct of any affiliate or representative of the governing body and/or employee having an outside interest in an entity providing services to the organization and/or other client/patient relationships.

In the event of proceedings that require input, voting, or decisions, the individual(s) with a conflict of interest must be excluded from the activity.

Evidence: Written Policies and Procedures
Written Minutes of Meetings

Standard 103, Criterion B: The written policy and procedure for conflict of interest disclosure will be shared and understood.

Interpretation: The conflict of interest disclosure policy and procedure must be shared with and understood by the governing body, staff members, and organization representatives.

Evidence: Response to Interviews
Board Meeting Minutes
Orientation Records
Signed Conflict of Interest Disclosure Statements
Standard 104. There is a designated individual, accountable to the governing body/owner, who is responsible for the overall operations and services of the organization.

Standard 104, Criterion A: There is an individual who is designated as responsible for the overall operation and services of the organization.

Interpretation: The leader/executive is responsible for all programs and services and must be accountable to the governing body. There will be written policies and procedures that specify the responsibilities and authority of this individual.

The administrator organizes and directs the agency’s ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. The resume and/or application of the current leader/executive verify that the individual who holds this position meets the minimum education and experience requirements as defined by the organization and any applicable state and federal laws and regulations. The organization must also provide information regarding changes in the administrator position to ACHC and other required agencies.

Evidence: Written Policies and Procedures
Leader/Executive Resume/Application

Standard 104, Criterion B: An individual is appointed to assume the role of the leader/executive during temporary absences and/or vacancies.

Interpretation: There must be a person or designated position appointed to assume the role of the leader/executive for temporary absences and/or vacancies. This appointment must be written into operations policy and must be included in the job description of the position intended to perform this responsibility. The duties that the individual assumes during the absence of the leader/executive must be written into operations policy and into the orientation of this individual.

Evidence: Written Policies and Procedures

Standard 105: Service personnel can accurately describe the chain of command.

Interpretation: Personnel must be able to provide a description of the organization’s chain of command that is consistent with the organization chart.

Evidence: Response to Interviews

Standard 106: There is a written organization mission and philosophy statement that directs the services and goals of the organization.

Interpretation: There is a written organization mission and philosophy statement that directs the goals and service/care delivery activities of the organization. The organization regularly reviews the mission and philosophy statements. The mission and philosophy are communicated to all staff.

Evidence: Written Mission and Philosophy Statement
Response to Interviews

Standard 107. The organization complies with all federal, state, and local laws and regulations

ACHC, Inc Effective: 08/17/09
and reports compliance outcomes.

Standard 107, Criterion A: There are written policies and procedures established and implemented by the organization regarding compliance with all applicable federal, state, and local laws and regulations. The organization also complies with accepted professional standards and practices.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: This standard requires compliance with all laws and regulations such as local and state licensure, professional licensure/certification, practice standards, the Americans with Disabilities Act, Equal Employment Opportunities Act, Fair Labor Standards Act, Title VI of the Civil Rights Act of 1963, Occupational Safety and Health Standards, Medicare regulations, Medicaid regulations, Omnibus Budget Reconciliation Act 1987, Balanced Budget Act of 1997, occupational licensure laws, Public Health regulations relating to infectious diseases, HIPAA regulations and other laws and regulations as applicable to the service/care provided by the organization.

Compliance with Civil Rights and Equal Employment Opportunity Acts is required for organizations receiving State or Federal funds (Medicare, Medicaid, Title III, Title XX, etc.).

Compliance with OSHA, FDA, DEA, Dept. of Transportation, State Dept. of Agriculture, all appropriate occupational licensing boards, and all required business licenses for city, county, and state are required for all organizations as applicable to the service/care provided.

Accepted standards of practice and occupational licensure acts are utilized by the organization to guide the provision of service/care.

The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses and certificates must be displayed in an area accessible to customers and patients. The supplier shall provide copies upon request, to government officials or their authorized agents

The supplier shall provide only durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The supplier shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom-fabricated item.

Evidence: Written Policies and Procedures
Copies of Appropriate Licenses
Copies of all Applicable Occupational Licensure Acts, Rules, and Standards of Practice
Copies of Required Posters in a prominent location
Observation

Standard 107. Criterion B: The organization will inform the accrediting body and Board of Directors of any negative outcomes from review/audits.

Interpretation: Negative outcomes affecting accreditation or licensure will be reported to the governing body/owner and to ACHC within 30 days. All responses and actions to the outcomes will be included in the report.

Outcomes that must be reported to ACHC include, but are not limited to: license suspension(s); license probation; conditions/restrictions to license(s); and civil penalties of ten thousand dollars ($10,000.00) or more.
Standard 108. Descriptions of specific service/care provided by the organization are available to all staff, clients/patients, and the community.

Interpretation: Marketing materials and/or handouts must include: (1) types of service/care available; (2) service/care limitations; (3) charges or client/patient responsibility for service/care and/or products before or at time of delivery (or indication that charges are available upon request); (4) eligibility criteria; (5) hours of operation, including on call availability (if applicable); and (6) contact information and referral procedures.

Written descriptions of service/care with detailed information must be available to staff members. Marketing and instructional materials must use lay language and provide a more general description of services offered.

Descriptions must include each service/care provided to the client/patient. The contact information and referral procedures must provide instructions for telephoning the organization or an answering service and procedures to make a referral for services. Hours of operation must be included.

Standard 109. A written Client/Patient Bill of Rights is reviewed with and distributed to each recipient of in-home service/care. The agency protects and promotes the exercise of these rights.

Standard 109, Criterion A: There are written policies and procedures established and implemented by the organization regarding the rights and responsibilities of clients/patients.

Interpretation: Written policies and procedures outline the client/patient rights and responsibilities. The policy shall require that the organization provide the client/patient with a written copy of their rights before initiation of service/care. The policy must state that if a client/patient cannot read the statement of rights, it shall be read to the client/patient in a language the client/patient understands. For a minor or a client/patient needing assistance in understanding these rights, both the client/patient and the parent, legal guardian, or other responsible person must be fully informed of these rights. An agency that provides advance directives information must provide written information concerning its policies on advance directives, prior to care being provided.

The Client/Patient Bill of Rights must include, but not be limited to the right to:

- Be fully informed in advance about service/care to be provided, including the disciplines that furnish care and the frequency of visits as well as any modifications to the service/care plan.
• Participate in the development and periodic revision of the plan of service/care.
• Informed consent and refusal of service/care or treatment after the consequences of refusing service/care or treatment are fully presented.
• Be informed, both orally and in writing, in advance of service/care being provided, of the charges, including payment for service/care expected from third parties and any charges for which the client/patient will be responsible.
• Have one’s property and person treated with respect, consideration, and recognition of client/patient dignity and individuality.
• Be able to identify visiting staff members through proper identification.
• Voice grievances/complaints regarding treatment or care, lack of respect of property or recommend changes in policy, staff, or service/care without restraint, interference, coercion, discrimination, or reprisal.
• Have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated.
• Choose a health care provider.
• Confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information.
• Be advised on agency’s policies and procedures regarding the disclosure of clinical records
• Receive appropriate service/care without discrimination in accordance with physician orders.
• Be informed of any financial benefits when referred to an organization.
• Be fully informed of one’s responsibilities.
• Be informed of provider service/care limitations.

When state or federal regulations exist regarding client/patient Bill of Rights, the organization’s Bill of Rights statement must include those components. The client/patient has the right to be informed of his or her rights. The organization must protect and promote the exercise of these rights.

Evidence: Written Policies and Procedures
Client/Patient Bill of Rights
Response to Interviews

Standard 109, Criterion B: All staff members are provided training during orientation and at least annually thereafter concerning the organization’s client/patient Bill of Rights.

Interpretation: All staff must receive training regarding client/patient Bill of Rights upon hire and annually.

Evidence: Orientation and In-Service Records
Response to Interviews

Standard 109, Criterion C: The written client/patient Bill of Rights and Responsibility statement will be discussed and distributed to the client/patient at the time of the admission.

Interpretation: The Client/Patient Bill of Rights and Responsibility statement must be reviewed with the client/patient or responsible party. Documentation of receipt and understanding of the information must be placed in the client/patient record. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient record that the Client/Patient Bill of Rights was reviewed and understood by the client/patient/responsible party. A copy of the Bill of Rights and Responsibilities is made available to others in the community upon request.

Evidence: Client/Patient Records
Response to Interviews

Standard 109, Criterion D: DMEPOS Supplier Standards are distributed to and reviewed with each Medicare recipient of service/care.

Interpretation: A copy of the DMEPOS Supplier Standards must be distributed to the client/patient/responsible party with documentation of receipt and understanding of the information. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient/responsible party record that the DMEPOS Supplier Standards were reviewed and understood by the client/patient/responsible party.

Evidence: Client/Patient Records

Response to Interviews

Standard 110. The organization will maintain and follow their written grievance, complaint, and concern policy and procedure.

Standard 110, Criterion A: The organization written policies and procedures require that the client/patient be informed at the initiation of service/care how to report grievances, complaints, or concerns and explain how they will be investigated and resolved.

Interpretation: The organization must have a written procedure that describes how client/patient grievances, complaints, and concerns will be investigated and resolved. Policy and procedure will describe at a minimum: (1) the appropriate person to be notified of the grievance/complaint/concern; (2) time frames for investigation activities, to include after hours; (3) reporting of information; (4) review and evaluation of the collected information; (5) effective action taken and outcome; (6) communication with the client/patient/caregiver/family; and (7) documentation of all activities involved with the grievance/complaint/concern, investigation, analysis and resolution. The organization will investigate and attempt to resolve all client/patient grievance/complaint/concern and document the results within a described time frame as defined in policy.

Evidence: Written Policies and Procedures

Response to Interviews

Standard 110, Criterion B: All personnel are knowledgeable of the policy and procedure for handling a grievance/complaint/concern during any contact with clients/patients.

Interpretation: Personnel will be oriented and familiar with the client/patient grievance/complaint/concern policy and procedure. Staff will assist in implementing the resolution process as needed.

Evidence: Personnel Orientation Checklist

Response to Interviews

Standard 110, Criterion C: Within five (5) calendar days of receiving a beneficiary's complaint, a supplier shall notify the beneficiary, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and that it is investigating. Within 14 days, the supplier shall provide written notification to the beneficiary of the results of its investigation and response. The supplier shall maintain documentation of all complaints that it receives copies of the investigations, and responses to beneficiaries.

Interpretation: The organization will maintain records of grievances/complaints and their outcomes, and include this information in the annual program service/care review/evaluation. A summary of the grievances/complaints will be reported quarterly in the performance management plan.
Evidence: Grievance/Complaint Records and/or Files

Response to Interviews

Standard 110, Criterion D: The organization must provide the client with written information concerning how to contact the organization, appropriate state agencies, and ACHC concerning grievances/complaints at time of admission.

The organization must provide all client/patient with written information listing a telephone number, contact person, and the organization’s process for receiving, investigating and resolving grievances/complaints about its service/care.

The agency must advise the patient in writing of the telephone number of the appropriate state regulatory body’s hot-line telephone number(s), the hours of operations and the purpose of the hotline. This may be a separate information sheet given to the client/patient or incorporated with the Client/Patient Bill of Rights information. ACHC’s telephone number must be provided. Note: The ACHC phone number requirement is not applicable to organizations if this is their first ACHC survey.

Evidence: Client/Patient Records

Standard 111. There are written policies and procedures regarding confidentiality and privacy of client/patient information.

Standard 111, Criterion A: There are written policies and procedures for securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

Interpretation: Confidentiality policies address, at a minimum, the following: (1) a definition of protected health and confidential information, the types of information that are covered by the policy, including electronic, and computerized information, telephone and cell phone communications, and verbal and faxed information; and (2) persons/positions authorized to release PHI/EPHI and confidential information and person’s to whom it may be released; (3) conditions which warrant its release; (4) persons to whom it may be released; (5) signature of the client/patient or someone legally authorized to act on the client/patient’s behalf; (6) a description of what information the client/patient is authorizing the organization to disclose; (7) securing client/patient records and identifying who has authority to review or access clinical records; (8) when records may be released to legal authorities pursuant to subpoenas with appropriate documentation; (9) the storage and access of records to prevent loss, destruction or tampering of information; and (10) the use of confidentiality/privacy statements and who is required to sign a confidentiality/privacy statement. The organization has clearly established written policies and procedures that address the areas listed above which are clearly communicated to staff.

Evidence: Written Policies and Procedures

Standard 111, Criterion B: Personnel, governing body/owner are knowledgeable about and consistently follow confidentiality and privacy policies and procedures.
Interpretation: There is evidence that personnel and governing body/owner have been trained and practice confidentiality policies. The organization must designate an individual to be responsible for seeing that the confidentiality and privacy procedures are adopted and followed.

Evidence:
- Signed Confidentiality Agreements
- Orientation Checklists
- Job Descriptions
- Response to Interviews

Standard 111, Criterion C: The client/patient and/or responsible party receive and understand information related to the confidentiality policy prior to the receipt of services/care.

Interpretation: The individual visiting the client/patient/responsible party for the first time will provide written information and will discuss confidentiality/privacy of client/patient-specific information as included in the client/patient rights and responsibilities. Client/patient records must contain signed release of information statements/forms when the organization bills a third party payer or shares information with others outside the organization as required by HIPAA and other applicable law and regulations.

Evidence:
- Client/Patient Records
- Response to Interviews

Standard 111, Criterion D: The organization has Business Associate Contracts for all Business Associates that may have access to Protected Health Information as required by HIPAA and other applicable law and regulations.

Interpretation: A copy of all Business Associate Contracts will be on file at the organization.

Evidence: 
- Business Associate Contracts

Standard 112: Written policies and procedures describe resuscitative guidelines and the responsibilities of staff.

Interpretation: The organization has written policies and procedures for staff responsibilities regarding client/patient resuscitation and the response in the event of a medical emergency. The policies must identify which staff, if any, may perform resuscitative measures, response to medical emergencies and utilization of "911" services (EMS) for emergencies. Successful completion of appropriate training, such as CPR course(s) must be defined in the policies and procedures. Clients/patients and families are provided information about the organization's policies for resuscitation, medical emergencies and accessing "911" services (EMS).

Evidence:
- Written Policies and Procedures
- Response to Interviews
- Patient Education Materials
Standard 113. The organization has written policies and procedures for the reporting of suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children in accordance with state law.

Standard 113, Criterion A: The written policies and procedures define and outline the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Written policies and procedures incorporate state law in relation to reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Written Policies and Procedures

Standard 113, Criterion B: All staff members are knowledgeable of the policy and procedure for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Personnel will be oriented and familiar with the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Employee Orientation Checklist
Response to Interviews

Standard 113, Criterion C: The organization will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the appropriate authorities.

Interpretation: All staff members are knowledgeable of and will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the designated organization staff member who is responsible for reporting to the appropriate authorities.

Evidence: Incident Reports
Response to Interviews

Standard 114. The organization has mechanisms in place to investigate and make recommendations on specific ethical concerns and issues related to client/patient service/care.

Standard 114, Criterion A: The organization has written policies and procedures that address identification, evaluation, and discussion of ethical issues.

Interpretation: The organization provides service/care within an ethical framework that is consistent with applicable professional and regulatory bodies. Written policies and procedures must address the mechanisms utilized to identify, address, and evaluate ethical issues in the organization.

Evidence: Written Policies and Procedures

Standard 114, Criterion B: All personnel are knowledgeable of the policy and procedure for reporting ethical concerns to the organization’s management.
Interpretation: Orientation and annual training of personnel must include a list of potential ethical issues and the process to follow when an ethical issue is identified. Personnel are trained regarding professional relationships, conflict of interest, and professional boundaries.

Evidence: Personnel Orientation Checklist
In-Service Records
Response to Interviews

Standard 115. The organization has mechanisms in place to provide service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Standard 115, Criterion A: The organization has written policies and procedures that address the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Written policies and procedures describe the mechanism the organization will utilize to communicate to clients/patient and families of different nationalities. The policies and procedures will also describe any actions expected for staff members providing service/care to clients/patients who have different cultural backgrounds and beliefs.

Evidence: Written Policies and Procedures

Standard 115, Criterion B: All personnel are knowledgeable of the written policy and procedure for the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Different cultural backgrounds and beliefs impact the client’s/patient’s lifestyles, habits, view of health, healing, terminal illness, and dying. Organization staff must identify differences in their own beliefs and the client’s/patient’s beliefs and find ways to support the client/patient. Staff members must make efforts to understand how the client/patient and family’s cultural beliefs impact their perception of his illness approach to health and home care. If applicable, staff also considers the impact on end of life service/care issues, loss, and bereavement.

All staff members are provided with annual education and resources to increase their cultural awareness of the clients/patients/families they serve.

Evidence: Personnel Orientation Checklist
In-Service Training Records
Response to Interviews
Standard 116. The organization has a Compliance Program to prevent violations of the fraud and abuse laws.

Standard 116, Criterion A: There is an established Compliance Program and designates one or more individuals in leadership positions to address compliance issues.

Interpretation: The organization will have an established Compliance Program that provides both general and specific guidance as to various internal anti-fraud and abuse controls. The Compliance Program identifies and discusses numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program must detail actions the organizations must take to prevent violations of the fraud and abuse laws. The guidelines include the following: (1) implementation of written policies, procedures, and standards of conduct; (2) designation of a compliance officer and compliance committee; (3) conducting effective training and education programs; (4) development of open lines of communication between the compliance officer or compliance committee and organization employees for receiving complaints and protecting callers from retaliation; (5) performance of internal audits to monitor compliance; (6) establishing and publicizing disciplinary guidelines for failing to comply with organization standards and policies and applicable statutes and regulations; and (7) prompt response to detected offenses through corrective action.

Evidence:  Written Policies and Procedures  
            Compliance Plan  
            Internal Audits  
            Quality Improvement Activities  
            Orientation and In-Service Education Records  
            Response to Interviews
SECTION 200: FINANCIAL MANAGEMENT

Standard 201. There is an annual budget that includes all projected revenue and expenses for the organization’s programs.

Standard 201, Criterion A: The organization has written policies and procedures that address the budgeting process. The organization’s annual budget is developed by the governing body/owner.

Interpretation: The organization has a budget that includes projected revenue and expenses for all programs and service/care it provides. The budget is reflective of the organization’s service/care, strategic plan, and programs.

The organization’s leaders and the individuals in charge of the day-to-day program operations must be involved in developing the budget and in planning and review of periodic comparisons of actual and projected expenses and revenues for the service/care.

Evidence: Written Policies and Procedures
Copy of Current Annual Budget

Standard 201, Criterion B: The budget is reviewed and updated at least annually by the governing body and leadership staff of the organization.

Evidence: Copy of Annual Budget(s)
Response to Interviews

Standard 202. Fiscal policies and procedures describe activities to ensure sound business practices for program service/care operations.

Standard 202, Criterion A: There are written policies and procedures, which ensure sound business practices.

Interpretation: There must be written policies and procedures that address each of the following: (1) receipt and tracking of revenue; (2) billing of clients/patients/transmission to third party payers; (3) notification to the client/patient/family of changes in reimbursement from third party payers; (4) collection of accounts/reconciliation of accounts; (5) extension of credit; (6) consequences of non-payment, if applicable; (7) acceptance of gifts and/or restricted funds, if applicable; (8) process for receiving, recording and acknowledging mailed contributions, if applicable; and (9) assignment of revenue to the appropriate program. An organization which does not extend credit must state that there is no extension of credit and specify procedures for dealing with non-payment and partial payment situations.

Evidence: Written Policies and Procedures
Standard 202, Criterion B: There is an accounting system that tracks all revenue and expenses and reconciled charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits.

Interpretation: Organizations must have an accounting system or process that tracks all revenue and expenses.

A large, multi-faceted organization is not required to maintain a separate accounting system for the service/care program(s) being accredited.

Evidence: Accounting System

Standard 202, Criterion C: Financial hardship forms are completed if client/patient is unable to pay.

Interpretation: Appropriate documentation is completed if a client/patient is unable to pay.

Evidence: Client/Patient Records

Standard 203. The organization establishes the necessary time frames for keeping financial records.

Standard 203, Criterion A: All financial records are kept for the time frames described in financial record management policies and procedures and in compliance with regulatory standards.

Interpretation: Written policies and procedures reflect applicable statutes, IRS regulations, and/or Medicare/Medicaid program service/care requirements of maintaining financial records for at least five years after the last audited cost report.

Evidence: Written Policies and Procedures

Standard 204. There are written policies and procedures that require established rates for all program service/care and define methods for providing full reimbursement disclosure to the client/patient or other interested parties.

Standard 204, Criterion A: Written policies and procedures require established service/care rates and describe the method(s) for conveying charges to the public, consumers, and referral sources.

Interpretation: There are written policies and procedures for establishing and conveying the charges for the products and services/care provided to clients/patients. Written charges for services/care are available upon request.

Evidence: Written Policies and Procedures
A list of Services/Care with Corresponding Charges
Standard 204, Criterion B: All staff members responsible for conveying charges are knowledgeable of the policy and procedure.

Interpretation: Current charges for services/care are available in writing for reference by employees when conveying information to the client/patient, public, consumers, and referral sources.

All staff members responsible for conveying charges are oriented and provided with education concerning the conveying of charges.

Evidence: Orientation Checklist
          Response to Interviews

Standard 204, Criterion C: The client/patient and/or responsible party is advised orally and in writing of the charges for service/care at or prior to the receipt of services. The client/patient also has the right to be informed of changes in payment information no later than 30 days after the agency becomes aware of the change. Patients that are Medicare eligible are informed when Medicare assignment is accepted.

Interpretation: The client/patient/responsible party will be provided written information concerning the charges for service/care at or prior to the receipt of service/care. Client/patient records contain written documentation that the client/patient was informed of the charges, the expected reimbursement for third party payers, and the financial responsibility of the client/patient.

Evidence: Client/Patient Records
          Response to Interviews

Standard 204, Criterion D: There are criteria for the use of sliding fee scale.

Note: This criterion is required for organizations that utilize a sliding scale fee.

Interpretation: If the organization utilizes a sliding scale fee, there must be written criteria for determining eligibility for adjusted rates and methods used to determine the rate the client/patient would be expected to pay for service/care.

Evidence: Written Criteria for utilizing the Sliding Fee Scale
SECTION 300: HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Direct service/care personnel include anyone who has direct responsibility for client/patient/family service/care, including, but not limited to: contract personnel, delivery technicians, respiratory care practitioners, pharmacists, clinical supervisors, fitters, rehab tech supplies, and case managers.

Standard 301. There are written personnel policies and procedures describing the activities related to personnel management.

Standard 301, Criterion A: There are written policies and procedures that describe personnel policy management and the review of personnel policies.

Interpretation: Personnel policies must address: (1) wages; (2) benefits; (3) grievances; (4) recruitment, hiring and retention of personnel; (5) disciplinary action/termination of employment; (6) staff conflict of interest; and (7) performance expectations and evaluations. Personnel policies are reviewed at least annually and updated as needed and are in accordance with applicable law and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

It is preferred that wage information be available in the form of salary scales, with information about beginning salaries for each position classification, salary ranges, overtime, on-call and holiday pay.

An explanation of benefits must be shared with all benefit eligible employees. Organizations, which provide no benefits to some categories of employees, must communicate this fact in writing to affected employees. For example, the contract/agreement with home care staff who is utilized on an “as needed” basis may address that benefits are not available to persons employed in that classification.

Written grievance information must address options available to employees who have work-related complaints, including steps involved in the grievance procedure.

Disciplinary action and termination of employment policies must clearly define time frames for probationary actions, conditions warranting termination, steps in the termination process, and appeal procedures.

Evidence: Written Policies and Procedures and/or Employee Handbook
Response to Interviews

Standard 301, Criterion B: Personnel policies are accessible to employees.

Interpretation: Each employee must receive a copy of the company employee handbook or copies of all personnel policies. Any employee handbook and all personnel policies are reviewed at least annually and updated as needed.

Evidence: Employee Handbook and/or Personnel Policies
Personnel Files
Response to Interviews
Standard 302. There is a job description for each position within the organization.

Standard 302, Criterion A: There is a job description for each position within the organization which is consistent with the organization chart with respect to function and reporting responsibilities.

Interpretation: The job description lists: (1) job duties; (2) reporting responsibilities; (3) minimum job qualifications, experience requirements, education, and training; (4) requirements for the job; and (5) physical and environmental requirements with or without reasonable accommodation. If the owner is not involved in day to day operations, then that individual does not need a job description.

Written job descriptions are reviewed at least annually and updated as needed.

The organization's job descriptions are consistent with the organization chart with respect to function and reporting responsibilities.

Evidence: Job Descriptions
Organization Chart

Standard 302, Criterion B: Each employee reviews and/or receives a copy of their current job description upon hire and whenever the job description changes.

Interpretation: Receipt and/or review of the job description with the employee is a necessary part of the orientation process and must be repeated during the annual performance evaluation and whenever the job description changes. The organization will verify the receipt and review by giving each employee a copy of the job description and requiring the employee to sign a copy of the job description and placing it in the employee’s personnel file.

Evidence: Personnel Files
Response to Interviews

Standard 303. Employees are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the organization.

Standard 303, Criterion A: Written policies and procedures describe the activities required to verify education, training, and experience when selecting a new employee.

Interpretation: Persons hired for specific positions within the organization must meet the minimum qualifications for those positions in accordance with applicable laws or regulations, as well as the organization’s policies and the job description.

Prior education, training, and experience will be verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, licenses, certificates, and workshop attendance records.

Evidence: Written Policies and Procedures
Personnel Files
Job Descriptions
Standard 303, Criterion B: All new employee qualifications will be reviewed through previous employer reference checks.

Interpretation: At least two references will be obtained prior to hire. All employer references will address position held, dates of employment and eligibility for rehire if the reference is allowed to disclose this information. In the case of an applicant with no previous work experience, educational or personal references may be accepted. In the case of an applicant who was a prior employee of the organization, the applicant's previous employment history may serve as their reference.

While written reference checks are preferred, documentation of telephone references is acceptable.

Evidence: Personnel Files

Standard 303, Criterion C: Personnel credentialing activities are conducted at the time of hiring and annually to verify qualifications of all credentialed/licensed staff in the positions they hold.

Interpretation: The personnel file or other employee records will contain validation that credentialing information is obtained on an annual basis. Credentialing information includes a procedure for the review of professional occupational licensure, certification, registration or other training as required by state boards and/or professional associations for continued credentialing.

Evidence: Personnel Files

Standard 304. Employees will have appropriate TB screening, Hepatitis B vaccination or declination, a valid driver's license, and a criminal background check.

Standard 304, Criterion A: TB screening or verification that the employee is free of symptoms will be mandatory for direct care employees.

Interpretation: Tuberculin skin testing (PPD) must be performed on all direct care staff as recommended by CDC and OSHA guidelines based upon community and company TB incidence and prevalence rates. The organization's written policy and procedure must describe this process. Direct Care employees are employees that deliver equipment or provide care or service inside the home or face to face in a facility.

Evidence: Written Policies and Procedures
Personnel Files or other Confidential Employee Records

Standard 304, Criterion B: All direct care personnel will have access to Hepatitis B vaccine as each job classification indicates and as described in federal CDC and OSHA standards.

Interpretation: Hepatitis B vaccination program and post-vaccination antibody titer must be performed in accordance with CDC and OSHA guidelines. Employees must sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.

The following are circumstances under which an employer is exempted from making the vaccination available: (a) the complete Hepatitis B vaccination series was previously received; (b) antibody testing shows the employee to be immune; or (c) the vaccine cannot be given to the individual for medical reasons or the individual cannot receive antibody testing.

Evidence: Personnel Files or other Confidential Employee Records
Standard 304, Criterion C: All personnel, who are required to operate a motor vehicle in the
course of their duties, are required to have a valid state driver’s license appropriate to the type of
vehicle being operated in compliance with state laws and the organization’s policies.

Interpretation: Evidence of valid drivers’ licenses must be kept in personnel files, along with record of
all inquiries made on individual driving records (MVR) through the State Department of Motor
Vehicles. The organization must conduct a MVR check on each staff member who is required to
operate a motor vehicle in the course of his/her duties at the time of hire. It is preferred that the
organization recheck the MVR at least every 3 years to insure the driving records of the staff member
are clear of violations that may be of concern to the organization. Copies of valid Commercial Drivers
License (CDL), HAZMAT Endorsement and valid DOT physicals must be kept on file for employees
that require CDL’s.

Evidence: Personnel Files

Standard 304, Criterion D: The organization must carry an appropriate amount of vehicle
insurance when required to operate a motor vehicle in the course of their duties and in compliance
with state laws and the organization’s policies.

Interpretation: The organization must carry an appropriate amount of insurance on all company vehicles.
The organization’s insurance carrier will instruct the company on what is an appropriate amount of
insurance based on risk assessments.

Evidence: Written Policy and Procedures
Personnel Files
Company Vehicle Insurance Documents

Standard 304, Criterion E: All personnel providing direct client/patient service/care will have a
criminal record background check.

Interpretation: The organization must perform a criminal background check and a national sex offender
registry check, at the time of hire, for each employee providing direct client/patient’s service/care.

The organization must have a policy regarding special circumstances, if any, for hire of a person
convicted of a crime. The policy may include, but not be limited to: documentation of special
considerations, restrictions, or additional supervision.

Evidence: Written Policies and Procedures
Personnel Files

Standard 305. The organization maintains a personnel file for each employee.

Standard 305, Criterion A: Written policies and procedures describe the procedures to be used in
the management of personnel files and confidential records for each employee.

Interpretation: Written policies and procedures will describe: (1) employee positions having access to
the personnel file; (2) proper storage; (3) the required contents; (4) review requirements; and (5) time
frames for retention of personnel files.
The organization maintains a personnel file for each employee that will contain, at a minimum, an application, dated, and signed withholding statements, verification of citizenship status, and all other items noted in the standards/criterions.

The organization is required to have complete personnel records available for inspection by federal, state regulatory agencies and accreditation agencies.

Evidence: Written Policies and Procedures
Personnel Files

Standard 306. The organization assures that all employees receive orientation.

Standard 306, Criterion A: The organization has a written orientation plan for all new employees.

Interpretation: The written orientation plan must include the following, at a minimum: (1) review of the individual's job description and duties to be performed and their role in the organization; (2) organization chart/supervision; (3) mission/philosophy; (4) record keeping and reporting; (5) confidentiality and privacy of protected health information; (6) client/patient's rights; (7) conflict of interest; (8) written policies and procedures; (9) training specific to job requirements; (10) additional training for special populations (i.e.: nursing homes, pediatrics, disease processes with specialized care); (11) cultural diversity; (12) ethical issues; (13) professional boundaries; (14) quality improvement plan; and (15) OSHA requirements, safety and infection control.

The organization must have a checklist or other method to verify that the topics have been discussed with individual workers; and written policies and procedures describing the orientation process.

Evidence: Written Policies and Procedures
Orientation Checklist/Orientation Plan

Standard 306, Criterion B: The organization will designate trained personnel responsible for conducting orientation activities.

Interpretation: The orientation process includes a description of position(s)/qualifications representing trained personnel responsible for conducting orientation activities.

Evidence: Written Policies and Procedures and/or Job Description

Standard 306, Criterion C: All staff members participate in an orientation program appropriate to the classification of the employee and the service/care he/she will provide prior to assuming client/patient responsibilities.

Interpretation: Orientation is conducted with all staff and volunteers prior to their assuming client/patient service/care responsibilities. Staff members are oriented to their specific client/patient assignments.

The orientation is documented in the personnel files for all staff members and volunteers.

Evidence: Orientation Checklist or other Documentation of Attendance
Personnel Files
Standard 307. The organization assures that all employees receive training and/or demonstrate competence appropriate to job requirements.

Knowledge and skills can be acquired through a variety of methods such as classroom instruction, on-the-job observation and demonstration, self-instruction, internships, etc. The focus and type of training is directly related to the goals of the employee and/or the organization.

Standard 307, Criterion A: The organization assures that all staff members have received training and/or education and can competently perform the required client/patient service/care activities prior to being assigned to work independently.

Interpretation: The organization’s written policies must define the minimum education and training, licensure, certification, experience, and the minimum competencies, required for each service/care offered, as well as the method for documenting that personnel have received the required training (i.e. certificates, diplomas, etc).

The organization designs and implements a competency assessment program based on the service/care provided. Competency assessment must be an ongoing process and focus on the primary service/care, and/or therapies being provided. Competency assessment is conducted initially during orientation and annually thereafter. Validation of skills is specific to the staff member’s job responsibilities.

Procedures for determining that staff are competent to provide quality service/care must be in place and may be accomplished through observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment. All competency assessments and training must be sufficiently documented. A self-assessment tool alone is not acceptable. Peer review of clinical staff competency by like disciplines will be acceptable if defined by the organization. There must be a plan in place for addressing performance and education of staff when staff does not meet competency requirements.

Evidence:  Written Policies and Procedures
          Evidence of Competency Assessment
          Response to Interviews

Standard 307, Criterion B: Staff members are trained and/or have demonstrated competence to perform any new tasks/procedures prior to performing those tasks independently. Direct care staff are not allowed to perform any task for which they have been evaluated as unsatisfactory.

Interpretation: The organization has a process that assures that each direct service staff member has demonstrated competency in any new task before being assigned to that task. The organization also has a process to ensure that staff have been proven competent to perform task(s) after re-training has been provided.

Evidence:  Written Policies and Procedures
          Evidence of Competency Assessment for New Tasks/Procedures
          Response to Interviews
Standard 308. The organization implements an education plan for all personnel.

Standard 308, Criterion A: The organization has an in-service education plan that provides ongoing in-service education for all staff members.

Interpretation: In-service education refers to ongoing training provided by the employer to develop and maintain skills necessary for all staff members to perform their current job responsibilities. Organizations may provide this training directly or arrange for staff to attend sessions offered by outside sources. The in-service education plan is a written document that may outline program topics to be offered or designate how program topics will be identified for personnel throughout the year. The plan must be based on reliable and valid assessment of needs relevant to individual job responsibilities. Ongoing education activities include methods for obtaining information about staff learning needs, outcome data from competency assessments, and staff input about the effectiveness of the in-services provided. Education activities also include a variety of methods for providing staff with current relevant information to assist with their learning needs. These methods include provision of journals, reference materials, books, internet learning, in house lectures and demonstrations, and access to external learning opportunities.

All staff are required to have continuing education hours. The organization must have a written policy defining the number of hours of in-service or continuing education required for each classification of personnel. It is preferred that organizations encourage supervisors to attend in-service education programs to improve their supervisory skills. The organization must comply with all professional or occupational licensure laws for continuing education requirements and organization policy requirements regarding continuing education.

There is written documentation confirming attendance at in-service and/or continuing education programs.

As applicable, education programs must be designed to assist staff with work related issues of grief, loss and change, and pain and symptom management.

Evidence:  Written Policies and Procedures
                   Documentation of In-service Education Programs and Attendance
                   Documentation of Staff Attendance at Continuing Education Programs
                   Response to Interviews

Standard 309. Qualified personnel evaluate all staff members.

Standard 309, Criterion A: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at least annually and in accordance with state or federal regulations. All patient care is provided in compliance with professional standards and principals.

Interpretation: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at frequencies required by state or federal regulations. Industry principles and professional standards also used to determine appropriate staffing and care. If no regulation exists the evaluation must be performed at least once annually to assess that quality service/care are being provided. This activity may be performed as part of a supervisory visit. Written policies and procedures must define assessment items/standards. The evaluation(s) shall become part of the personnel record.
Standard 309, Criterion B: Written annual performance evaluations are completed for all personnel based on specific job descriptions.

Interpretation: The organization has written policies and procedures addressing individual performance evaluations for all staff and/or volunteers. These policies describe how performance evaluations are conducted, who conducts them, and when they are to be conducted. The policy must also identify any deviations to their policy, i.e. if the organization’s annual evaluation serves as the performance evaluation for the leader(s)/executive(s) of the organization. Evaluations involve both the supervisor and the individual in rating work performance based on performance criteria for their specific job description.

Annual performance evaluations are required for part-time staff members that have worked for six months or longer in a year.

Standard 309, Criterion C: The results of annual performance evaluations are shared with personnel.

Interpretation: A copy of the performance evaluation must be reviewed by the employee and signed by the individual performing the evaluation and the employee. Performance evaluation results must be shared with the employee by a face-to-face conference with the supervisor.

Standard 309, Criterion D: Action is taken when negative client/patient outcomes are directly related to staff performance.

Interpretation: An assessment is completed to determine the best course of action when negative client/patient outcomes are experienced due to staff performance. Based on this assessment, actions may include remedial training of the staff, reassignment of the staff, or limitation of the staff’s involvement in client/patient service/care or other appropriate actions. The actions taken must be documented in personnel records, variance reports or other appropriate documents.
Standard 310. Written contracts and/or agreements govern the components of services/care that are purchased from another entity resulting in shared responsibility for service/care delivery.

Note: This criterion is applicable to organizations that have contracts/agreements for shared responsibility components.

Standard 310, Criterion A: Written contracts/agreements are on file within the organization.

Interpretation: A contract or agreement is required whenever the organization sells or purchases services, personnel, training, or supervision from another organization/individual for direct or indirect client/patient service/care on an on-going or individual client/patient basis.

Evidence: Written Contracts and/or Agreements

Standard 310, Criterion B: Service/care contracts/agreements are reviewed and renewed as required in the contract.

Interpretation: The organization has an established process to review and renew contract/agreements as required in the contract. A mechanism to indicate that the review and or renewal have been accomplished may be evidenced by either a notation of the review dates on the initial contract/agreement or development of an updated contract/agreement.

Evidence: Written Contracts and/or Agreements

Standard 310, Criterion C: There are copies of professional liability insurance certificates of coverage on file for any personnel providing direct service/care and/or organizations providing shared responsibility service/care.

Interpretation: The organization maintains current copies of professional liability insurance certificates of coverage for all personnel providing direct service/care and/or organizations providing shared responsibility service/care. The certificates should be maintained with the respective contract.

Evidence: Copies of current Insurance Certificates confirming liability coverage

Standard 310, Criterion D: Contracts/agreements contain the required items.

Interpretation: The following items must be included in the contract/agreement: (1) Name and type of service/care to be provided; (2) duration of contract/agreement; (3) responsibilities of each organization; (4) the manner in which service/care will be controlled, coordinated, and evaluated by the primary organization; (5) the amount and procedures for payment for service/care furnished under the contract; (6) compliance with all organization policies including applicable personnel policies; (7) requirements to meet Medicare Conditions of Participation; if applicable, (8) overall responsibility for supervision of staff, if applicable and (9) other applicable law and regulations.

Evidence: Written Contracts and/or Agreements
SECTION 400: CONSUMER SERVICES/RECORDS

Standard 401. An accurate record is maintained for each client/patient.

Standard 401, Criterion A: The organization has written policies and procedures relating to the required contents of client/patient records.

Interpretation: The organization's written policies and procedures must define the required contents of the client/patient records the organization maintains. The contents must include, but are not limited to the following: (1) identification data; (2) emergency contact; (3) name of primary caregiver(s); (4) source of referral; (5) name of physician responsible for care; (6) diagnosis; (7) physician's orders; (8) signed release of information and other documents for protected health information; (9) admission and informed consent documents; (10) assessment of the home, if applicable; (11) initial assessments, if applicable (12) ongoing assessments, if applicable. A separate record must be kept for each client.

For programs providing clinical service/care (i.e.: Clinical Respiratory Care), the client/patient record must also include: (13) advance directives; (14) names of power of attorney and/or healthcare power of attorney; (15) evidence of coordination of service/care provided by the organization with others who may be providing service/care; (16) physician orders that include medications and dietary, treatment and activity orders; (17) signed and dated clinical and progress notes; (18) copies of summary reports sent to physicians; (19) client/patient/family response to service/care provided; and (20) a discharge summary, if applicable.

Evidence: Written Policies and Procedures

Standard 401, Criterion B: Written policies and procedures address access, storage, removal, and retention of client/patient records and information.

Interpretation: Organizational policies must be consistent with HIPAA standards. Policies must define who can have access to client/patient records, including persons authorized to enter information and review the records. Original copies of all active client/patient records must be kept in a secure location on the organization's premises. Current electronic client/patient records must be stored in an appropriate secure manner as to maintain the integrity of the client/patient data through routine backups on or off site. The organization's policies specify any circumstances and the procedure to be followed to remove client/patient records from the premises or designated electronic storage areas. Policies describe the protection and access of computerized records and information, including back-up procedures, electronic transmission procedures, storage of back-up disks and tapes and methods to replace information if necessary.

Clinical record information is safeguarded against loss of unauthorized use. An organization must have written consent from the patient to release information not authorized by law. Written procedures govern use and removal of records and the conditions for release of information.

All client/patient records must be maintained in accordance with all applicable state and federal laws and rules.

 Portions of client/patient records may be copied and removed from the licensed premises to ensure that appropriate service/care staff will have information readily accessible to them to enable them to provide the appropriate level of service/care.

Evidence: Written Policies and Procedures
Standard 401, Criterion C: Client/patient records contain documentation of all service/care provided with entries dated and signed.

Interpretation: The client/patient record must contain documentation of all service/care provided, directly or by contract, with entries dated and signed by the appropriate staff member. Each home visit, treatment, or service/care must be documented in the record and signed by the individual who provided the service/care. Signatures must be legible, legal and include the proper designation of any credentials.

Evidence: Client/Patient Records

Standard 402. There is a process for client/patient referral and acceptance.

Standard 402, Criterion A: There are written policies and procedures, which describe the referral process.

Interpretation: Written policies and procedures describe the referral process including the required referral information. Written policies and procedures designate the positions in the organization that may receive referrals.

Referrals containing verbal orders must be given by the referring physician, by others approved by law to prescribe, or the individual directly designated to convey orders and will be referred to a designated staff member(s) for verification and documentation of verbal orders.

Evidence: Written Policies and Procedures

Standard 402, Criterion B: There are written policies and procedures for service/care guidelines, which define eligibility for all service/care and programs.

Interpretation: There are written policies and procedures that designates the staff member(s) that are assigned to assess the level and type of service/care required by clients/patients referred to the organization, and determine whether the client/patient is eligible for admission based on the organization’s criteria and availability of service/care to meet the client/patient’s needs.

Eligibility guidelines must identify the following: (1) target population(s); (2) geographic area served; (3) service/care limitations; and (4) method of payment. Eligibility guidelines may vary for different service/care programs. Eligibility criteria are periodically reviewed for appropriateness and continued accessibility to the organization’s programs. Specialized populations may be defined generally as anyone needing the service/care, or in some cases, may be defined by special funding sources, specific ages (elderly, infants, children, etc.), special service/care needs (medical care, homemaking, personal care, etc.), or specific diseases/disabilities (Alzheimer’s, arthritis, etc.). The organization shall identify the geographic area served.

Service/care may have limitations such as client/patient-related restrictions (provided only to ambulatory patients, provided only when client/patient cannot perform personal care tasks independently, limited life expectancy, availability of a responsible caregiver, safety restrictions etc.), or organization-related restrictions (ability of staff, hours of operation, etc.). Policies describe eligibility guidelines and procedures to follow for clients/patients who have no ability to pay for service/care.

Evidence: Written Policies and Procedures

Standard 402, Criterion C: There are written policies and procedures that address the organization’s compliance with federal, state, and local anti-discrimination laws in the acceptance of clients/patients.
Interpretation: There must be written policies and procedures verifying the organization's intent to abide by anti-discrimination legislation which must include, but not be limited to the following: age, race, nationality, creed, sex, sexual orientation, diagnosis/infectious disease, disability, ability to pay, and DNR status.

Evidence: Written Policies and Procedures

**Standard 402, Criterion D: Client/patient records and other sources provide verification that the clients/patients receiving service/care meet eligibility requirements.**

Interpretation: Client/patient records and other sources provide verification that clients/patients receiving service/care meet eligibility requirements.

Evidence: Client/Patient Records

**Standard 402, Criterion E: Client/patient is provided with information regarding expected time frames for delivery of equipment.**

Interpretation: Clients/patient's notified at time of referral when equipment/supplies will be delivered.

Evidence: Client/Patient Record

**Standard 403. The organization coordinates planning and service/care delivery efforts with other community agencies.**

**Standard 403, Criterion A: There are written policies and procedures for addressing client/patient needs, which cannot be met by the organization. Clients/patients are referred to other agencies when appropriate. The prescribing physician and/or referral source is notified within 3 days if the equipment or services ordered cannot be provided.**

Interpretation: Service/care needs which cannot be met by the organization will be addressed by referring the client/patient to other organizations when appropriate. Client/patient records or referral or intake forms must indicate a referral was made to another organization or communication was provided to the physician or referral source when client/patient needs could not be met.

Evidence: Written Policies and Procedures

**Client/Patient Records or Referral Log or Intake Form**

**Standard 403, Criterion B: All staff members are knowledgeable about other service/care available in the community.**

Interpretation: All staff members are aware of other community service/care and make an effort to work cooperatively with these organizations to promote a full range of home and community based service/care options in the communities served. Service/care needs, either identified by staff, referring physicians, or requested by clients/patients/families/responsible party, which cannot be met by the organization will be addressed by referring the client/patient/family to other community agencies.

Evidence: Client/Patient Records

Response to Interviews
SECTION 500: QI/Performance Management

Standard 501. There is organizational participation and involvement in quality improvement activities by all staff members.

Standard 501, Criterion A: The organization ensures the implementation of a quality outcome/improvement plan by the designation of a person or persons responsible for quality improvement coordination activities.

Interpretation: Duties and responsibilities relative to QI coordination include: assisting with the overall development and implementation of the QI plan; assisting in the identification of goals and related client/patient outcomes; and coordinating, participating, and reporting of activities and outcomes results.

The individual(s) responsible for quality improvement coordination activities may also be the owner, manager, supervisor, or other organization employee.

Evidence: Job Description

Standard 501, Criterion B: There is evidence of involvement of the governing body/owner.

Interpretation: The governing body and leaders are ultimately responsible for all actions and activities of the organization; therefore, their role in the evaluation process and the responsibilities delegated to staff must be clearly documented. There must be evidence that the results of quality improvement activities are communicated to the governing body and organizational leaders.

The organization’s leaders allocate resources for implementation of the quality improvement program. Resources may include but are not limited to training and education programs regarding quality improvement, staff time, information management systems, and computer programs.

Evidence: Response to Interviews
Meeting Minutes

Standard 501, Criterion C: There is evidence of staff involvement in the quality improvement process.

Interpretation: Personnel will receive training related to quality improvement activities and their involvement. Training may include, but not be limited to, the purpose of quality improvement activities, person(s) responsible for coordinating quality improvement activities, the staff’s individual role in quality improvement, and performance improvement outcomes resulting from previous activities.

The staff must be involved in the evaluation process through carrying out quality assessment activities, evaluating findings, recommending action plans, and/or receiving reports of findings. Staff must be informed of results of quality improvement activities that directly impact or reflect the service/care they provide.

Evidence: Minutes of Staff Meetings
Response to Interviews
Standard 502. There is a quality improvement program that includes all quality aspects of the program and service/care provided.

Standard 502, Criterion A: Quality improvement activities must include an annual evaluation of the program service/care.

Interpretation: An annual evaluation is a process that measures the organization's performance in relation to its mission, philosophy, goals and objectives and in meeting the needs of the clients/patients and communities served. As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote quality patient care. The annual evaluation is summarized in a written report which includes: (1) the effectiveness of the quality improvement program; (2) the effectiveness, quality and appropriateness of service/care provided to the clients/patients, service/care areas and community served, including culturally diverse populations; (3) effectiveness of the overall administrative and fiscal operations; (4) effectiveness of all programs including service/care provided under contractual arrangements; (5) utilization of staff; and (6) review and revision of policies and procedures, and forms used by the organization.

Evidence: Annual Program Evaluation

Standard 502, Criterion B: The organization investigates all adverse events.

Interpretation: The organization investigates all adverse events and develops a plan of correction to prevent the same or similar events from occurring again.

Adverse events include but are not limited to: (1) unexpected death, including suicide of client/patient/caregiver; (2) any act of violence, including rape of staff and/or client/patient/caregiver; (3) a serious injury (specifically includes loss of limb or function); (4) inadequate or malfunctioning equipment; (5) adverse effect to patient/client as a result of untimely delivery.

Evidence: Adverse Event Reports and Action Plans

Standard 502, Criterion C: Quality improvement activities must include ongoing monitoring of at least one important aspect related to the service/care provided.

Interpretation: The organization must conduct monitoring of at least one important aspect of the service/care provided by the organization. An important aspect of service/care reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of clients/patients), high risk (causes a risk of serious consequences if the service/care is not provided correctly), or problem-prone (has tended to cause problems for staff or clients/patients in the past.)

Examples of activities may include, but not be limited to: delivery of service/care (timeliness, incorrect product deliveries, etc.), medication administration, and clinical procedures.

Evidence: Quality Improvement Reports
Standard 502, Criterion D: Quality improvement activities must include ongoing monitoring of billing and coding errors.

Interpretation: The organization tracks the number of billing inconsistencies found through chart reviews as well as errors found through Medicare claims denied.

Evidence: Quality Improvement Reports

Standard 502, Criterion E: Quality improvement activities must include satisfaction surveys.

Interpretation: The QI plan identifies the process for conducting client/patient satisfaction surveys. The QI plan also identifies the process for conducting staff, physician, and referral source satisfaction surveys.

Evidence: Quality Improvement Reports

Standard 502, Criterion F: The quality improvement plan includes a review of the client/patient record.

Interpretation: The client/patient record review is conducted by all disciplines or members of the client/patient service/care team. An adequate sampling of open and closed records is selected to determine the completeness of documentation.

Evidence: Quality Improvement Reports

Standard 502, Criterion G: QI activities include ongoing monitoring of patient complaints about products and/or services.

Interpretation: QI activities include ongoing monitoring of patient complaints and the action(s) needed to resolve complaints and improve client/patient service/care.

Evidence: Quality Improvement Reports
Complaint logs

Standard 503. The organization uses appropriate methods to collect data and monitor performance.

Standard 503, Criterion A: Each quality improvement activity or study contains the required items.

Interpretation: Each quality improvement activity/study must include the following items: (1) a description of indicator(s)/activities to be conducted; (2) frequency of activities; (3) designation of who is responsible for conducting the activities; (4) methods of data collection; (5) acceptable limits for findings; (6) who will receive the reports; and (7) plans to re-evaluate if findings fail to meet acceptable limits in addition to any other activities required under state or federal laws or regulations.

Evidence: Quality Improvement Activities/Studies

Standard 504. Information gained from the quality improvement activities and evaluation is...
Standard 504, Criterion A: There is a written plan of correction developed in response to any quality improvement findings that do not meet an acceptable threshold.

Interpretation: A written plan of correction is developed in response to any quality improvement activity that does not meet an acceptable threshold. The plan of correction may identify changes in policy, procedure, or processes that will improve performance.

The plan of correction may require governing body action or approval or may be within the scope of authority already delegated to organization staff.

Evidence: Written Corrective Action Plans

Standard 504, Criterion B: Plans of correction indicates changes or revisions in the service/care, policies, and/or procedures.

Interpretation: A written summary describes changes made as part of a corrective action plan. This summary may be found as a separate document, as part of the minutes of governing body meetings, or as part of quality assessment reports.

Evidence: Quality Improvement Reports
Minutes of Governing Body Meetings

SECTION 600: PRODUCT SAFETY
Standard 601. The organization has a program designed to identify, prevent, and control infections.

Standard 601, Criterion A: The organization has written policies and procedures that address infection control and the compliance with regulatory standards.

Interpretation: Written policies and procedures, in accordance with CDC, Health Department, APIC (Association for Professionals in Infection Control Epidemiology) and OSHA standards, address education of staff, volunteers, clients/patients and caregivers about: (1) general infection control measures appropriate for service/care provided; (2) hand washing; (3) use of universal precautions and personal protective equipment; (4) needle-stick prevention and safety plan; if applicable (5) appropriate cleaning/disinfecting procedures; (6) infection surveillance, monitoring and reporting of employees and clients/patients; (7) disposal and transportation of regulated waste, if applicable; (8) precautions to protect immune-compromised clients/patients; (9) employee health conditions limiting their activities; and (10) assessment and utilization of data obtained about infections and the infection control program.

The organization has written policies and procedures that detail OSHA Blood borne Pathogen and TB Exposure Control Plan training for all direct care staff. The exposure control plans must be reviewed annually and updated to reflect significant modification in tasks or procedures that may result in occupational exposure. The Exposure Control Plan must include engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent, i.e. use of safer medical devices, and appropriate respiratory protection devices. A copy of the plans must be made available to the employee at the workplace during the work shift.

The TB Exposure Control plan must include a current organization assessment indicating the community and company TB incidence and prevalence rates as recommended by CDC guidelines.

Written policies and procedures identify the staff member who has the responsibility for the implementation of the infection control activities, and staff education.

Written policies and procedures describe the conditions limiting the employee’s assignments to office or home. Examples may be impetigo, communicable disease, fevers, respiratory diseases, etc.

Evidence: Written Policies and Procedures
Observation
Home Visits

Standard 601, Criterion B: All staff members, clients/patients, and caregivers are knowledgeable of the policies and procedures for infection control.

Interpretation: The organization must ensure staff members, volunteers, clients/patients and caregivers receive instruction about basic and high-risk infection control procedures as appropriate to the services/care provided. Training is consistent with OSHA and CDC recommendations: Clinical staff must provide infection control instructions to the client/patient/family and caregivers.
Standard 601, Criterion C: All staff members and volunteers must consistently follow infection control procedures in the provision of service/care to the organization’s clients/patients.

Interpretation: All staff members and volunteers demonstrate infection control procedures in the process of providing service/care to clients/patients as described in OSHA and CDC standards and as adopted into program service/care policies and procedures.

Standard 602. The organization has a system designed to identify, prevent, and control safety hazards related to the service/care provided to the client/patient.

Standard 602, Criterion A: The organization has written policies and procedures that address safety issues relating to service/care provision and education of staff members concerning safety. Interpretation: Written policies and procedures must include types of safety training as well as the frequency of training. Safety training is included at orientation and ongoing training. Safety training activities may include but not be limited to: (1) body mechanics; (2) workplace fire safety management and evacuation plan; (3) workplace or office security; (4) personal safety techniques; (5) common environmental hazards, (i.e. icy parking areas and walkways, blocked exits, cluttered stairways, etc.); (6) office equipment safety; and (7) safety and compliance monitoring measures relating to the client/patient’s medication, when applicable.

For programs providing in-home service/care, the safety training activities may also include: (1) personal safety techniques relating to in home service/care; (2) safety measures relating to oxygen use, if applicable; (3) client/patient medical equipment safety; if applicable (4) basic home safety measures (i.e., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits, bathroom safety, electrical safety, etc.); and (5) use of restraints, if applicable.

Standard 602, Criterion B: The organization educates all personnel about safety issues relating to service/care provision.

Interpretation: The organization has a process in place to educate personnel about home and workplace safety measures. Safety measures address building safety and security, staff safety and security, equipment safety, client/patient/family safety and security and home safety.

Standard 603. The organization has a plan to meet client/patient needs in a disaster or crisis situation.
Standard 603, Criterion A: The organization has written policies and procedures that outline the process for meeting client/patient needs in a disaster or crisis situation.

Interpretation: The written policies and procedures describe a process to organize and mobilize staff adequate to secure resources needed to meet client/patient needs in the event of a disaster or crisis. The process includes a system to identify alternative methods for contacting staff and mobilizing resources to meet critical client/patient needs. The process includes alternative methods, resources, and travel options for the provision of service/care and safety of staff and identified time frames for initiation of the plan. The supplier shall have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster.

The process includes specific measures for anticipated emergencies typical or appropriate for the geographical area served (i.e., hurricanes, tornadoes, floods, earthquakes, chemical spills, and inclement weather). The organization must have, at a minimum, an annual practice drill to evaluate the adequacy of their plan.

The emergency plan also describes access of 911 services in the event of needed emergency services/care for clients/patients, personnel, and visitors.

The program also has a method to identify and prioritize clients/patients based upon their need so that service/care is ensured for clients/patients who would otherwise be at risk of threat to their health or safety.

Evidence: Written Policies and Procedures

Standard 603, Criterion B: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation.

Interpretation: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation. The staff education requirements must include at a minimum; (1) orientation to the emergency plan; and (2) annual review of the emergency plan.

Evidence: Orientation Records In-Service Records Response to Interviews

Standard 604. Services/care is provided in a safe and secure environment.

Standard 604, Criterion A: The organization has written policies and procedures that address the organization’s fire safety and emergency power systems.

Interpretation: The written policies and procedures or fire safety plan address fire safety and management for all client/patient service/care areas, office and worksite environments. The written policies and procedures include the organization’s policies for providing emergency power to critical areas.

Evidence: Written Policies and Procedures Observation
Standard 604, Criterion B: The organization implements its fire safety and emergency power system plan.

Interpretation: Smoke detectors, fire alarms, and extinguishers are present and placed in secure areas to meet NFPA and LSC Code, (National Fire Protection Agency and Life Safety Code). These items are inspected, maintained and tested on a regular basis and as recommended by the manufacturer. Fire drills are conducted at least annually. The organization evaluates their response to the fire drill and communicates these results to personnel.

Evidence: Observation
Inspection/Maintenance Logs

Standard 605. The organization has a procedure for the safe transportation and labeling of hazardous chemicals and/or materials used in the provision of service/care.

Standard 605, Criterion A: The organization has written policies and procedures for the acceptance, transportation, and pick-up of hazardous chemicals and/or materials used in the provision of client/patient service/care.

Interpretation: Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal, and pick-up of hazardous wastes and hazardous chemicals and/or materials used in the home and organization. The organization must follow state and federal guidelines.

Evidence: Written Policies and Procedures

Standard 605, Criterion B: The organization has written policies and procedures following OSHA's Hazard Communication Standard that describe appropriate labeling of hazardous chemicals and/or materials, instructions for use, storage and disposal requirements.

Interpretation: The organization has written policies and procedures following OSHA's Hazard Communication Standard detailing: (1) the labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings; (2) the use of current Material Safety Data Sheet (MSDS) which must be maintained on file for each chemical used at the facility; and (3) the proper use, storage, and disposal of hazardous chemicals and/or materials, and (4) the use of appropriate personal protective equipment (PPE).

Evidence: Written Policies and Procedures
Review of MSDS Log

Standard 606. The organization has a system for identifying, monitoring, reporting, investigating, and documenting all variances.

Standard 606, Criterion A: The organization has written policies and procedures for identifying, monitoring, reporting, investigating, and documenting all incidents, accidents, variances, or unusual occurrences.

Interpretation: Written policies and procedures describe the process for reporting, monitoring, and investigating and documenting a variance. Procedures must describe: (1) action to notify the supervisor or after hours' personnel; (2) time frame for verbal and written notification; (3) appropriate
documentation and routing of information; (4) guidelines for notifying the physician; and (5) follow-up reporting to the administration/board.

There will be written policies and procedures for the organization to comply with the OSHA guidelines to include recording of information about every work-related injury or illness that involves loss of consciousness, restricted work activity, or job transfer, days away from work, or medical treatment beyond first aid.

There will be written policies and procedures for the organization to comply with the FDA’s Medical Device Tracking program and to facilitate any recall notices submitted by the manufacturer, if applicable.

Written policy identifies the person(s) responsible for collecting incident data and monitoring for patterns or trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

The organization defines incidents to be reported, including but not limited to: (1) Adverse client/patient service/care outcomes; (2) Personnel injury or endangerment; (3) Client/Patient/family injury, including falls; (4) Motor vehicle accidents when conducting agency business; (5) Environmental safety hazards, malfunctions or failures, including equipment; (6) Unusual occurrences.

There is an incident report form and identification of the types of situations that must be reported and documented. These would include but not be limited to personnel or client/patient injury during service provision, and adverse events.

Evidence: Written Policies and Procedures
Incident Report Form

Standard 606, Criterion B: Personnel demonstrate knowledge of the procedure for reporting and documenting variances involving self or client/patient.

Interpretation: The organization educates all personnel about examples of incidents/variances that may occur and the organizations policies and procedures for documenting and reporting incidents/variances.

Evidence: Orientation Records
In-Service Records
Response to Interviews

Standard 606, Criterion C: The supplier shall investigate any incident or injury in which DMEPOS may have contributed to the injury or incident, when the supplier becomes aware.

Interpretation: The investigation should be initiated within 24 hours after a supplier becomes aware of an injury or incident resulting in a beneficiary’s hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the items and services furnished and the adverse event.

Evidence: Incident Reports
SECTION 1700: PHARMACY SCOPE OF SERVICES

These standards are applicable to all the Pharmacy Scopes of Practice including Infusion Pharmacy, Ambulatory Infusion Center, Specialty Pharmacy and Respiratory Nebulizer Medication Pharmacy, except where noted.

Infusion Pharmacy is defined as a pharmacy that provides parenteral medications for patients in alternate settings. The service includes clinical monitoring by the pharmacy, and may include nursing services as well.

Ambulatory Infusion Center is defined as a centralized location where a patient can receive infusion therapy. The facility will be staffed by a nurse(s) and in some cases, a pharmacist. Services provided are ordered by an appropriate licensed provider (physician, nurse practitioner, physician assistant) as defined by state law.

Specialty Pharmacy is defined as a pharmacy that dispenses medications (typically self injectable drugs) to a patient's home, physician's office, or clinics specializing in certain chronic disease states. These medications benefit a targeted patient population with a chronic and sometimes life-threatening disease.

Respiratory Nebulizer Medication Pharmacy is defined as a pharmacy that dispenses aerosolized single patient dose respiratory medications. The medications may be prepackaged or compounded by the pharmacy. The medications are delivered directly to the patient's home by either the organization or by the use of outside delivery services such as UPS, FedEx or US Mail. The medications benefit a targeted patient population with chronic diseases such as Emphysema, Chronic Bronchitis or Asthma. Examples of Respiratory Medications include Beta Adrenergic Bronchodilators, Anticholinergic Bronchodilators, Cortico Steroids (Anti-inflammatory Agents), Cromolyn Sodium, Mucolytics, and Antibiotics.

Standard 1701. All Pharmacy Services will be provided by qualified pharmacists in accordance with state laws, regulations and recognized professional practice standards.

Standard 1701, Criterion A: All Pharmacy Services will be provided by qualified personnel and administered in accordance with the organization's policies and job descriptions, federal, state and local laws and established regulatory guidelines as dictated by the Board(s) of Pharmacy of the state(s) into which medications are dispensed.

Interpretation: Pharmacists and pharmacy technicians will function in accordance with the organization's job description, accepted ethical and professional practice standards and in accordance with all applicable federal, state and local laws and guidelines set by the Board of Pharmacy.

If Pharmacy Services are dispensed in other states, a pharmacy license or permit for states serviced will be obtained if required by that state (many states require a nonresident license). Current copies of applicable rules and regulations are available to appropriate organization staff.
Evidence: State Board of Pharmacy Regulations (for all states licensed)  
USP General Chapter <797>  
Pharmacist(s) Licenses  
Pharmacy Technician(s) Licenses/Certificates, where required  
Job Descriptions  
Personnel Record Review

**Standard 1701, Criterion B:** All required licenses and/or permits for the physical facility are current and placed on display in an appropriate public area.

Interpretation: The organization will display all licenses and/or permits required in the operation of the pharmacy services in an area of public view.

Evidence: 
- Resident State Board of Pharmacy Permit/License  
- Non-resident Board of Pharmacy Permit/License as required  
- DEA Registration  
- State Controlled Substance License (when required)  
- Pharmacist(s) Licenses  
- Pharmacy Technician(s) Licenses/Certificates, where required  
- Device Dispensing Permit (if required)  
- CLIA Certificate (if applicable)  
- State Board of Pharmacy License or contract with a locally licensed pharmacy (contract will be available for review during survey)  
- Biohazard generator permit or appropriate contract as required

**Standard 1702. There are written policies and procedures relating to pharmacy services.**

**Standard 1702, Criterion A:** There are written policies and procedures describing the scope of services offered by the pharmacy program.

Interpretation: The pharmacy program has written and implemented policies and procedures addressing the scope of services offered by the organization. These services should include, but not be limited to, types of services provided, target patient populations and goals of the program.

Evidence: Written Policies and Procedures

**Standard 1702, Criterion B:** Pharmacy Services are provided according to the patient's plan of care with access to a Registered Pharmacist available 24 hours a day, 7 days a week

Interpretation: The organization provides Pharmacy Services 24 hours a day, 7 days a week to meet patient needs. An on-call coverage system may be used to provide this coverage during evenings, nights, weekends and holidays. Written policy should define the on-call system used, back-up plan, and regular testing procedures. For organizations that have multiple employees on-call concurrently, written policy should define the sequence and method of notification to reach each discipline / employee on-call.
Evidence: On-Call Schedule/Log  
Written Policies and Procedures

Standard 1703. Qualified personnel supervise the pharmacy services.

Standard 1703, Criterion A: All Pharmacy Services are provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.

Interpretation: All Pharmacy Services must be provided under the direction of a registered pharmacist with sufficient education and experience in the scope of services offered. The policies and procedures identify the method and frequency for assessing pharmacist practice to ensure that services are provided appropriately.

Individual state boards of pharmacy and/or USP Chapter <797> list requirements for pharmacist training.

Evidence: Personnel Record Review  
Pharmacist(s) Licenses  
Written Policies and Procedures  
Response to Interviews

Standard 1703, Criterion B: A Registered Pharmacist supervises Pharmacy Technicians in accordance with organizational policy and the state Board of Pharmacy.

Interpretation: The pharmacy follows their state Board of Pharmacy regulations and organizational policies and procedures that demonstrate supervision of services provided by pharmacy technicians. The policies and procedures identify the method and frequency for assessing pharmacy technician practice to ensure that services are provided appropriately.

Evidence: Written Policies and Procedures  
Documentation of Supervision Activities - Patient Record and/or Personnel Record Review  
Response to Interviews

Standard 1703, Criterion C: Verification of license/certification of the referring physician or others approved by law to prescribe medical services, treatments, and/or pharmaceuticals will be conducted prior to providing service/care.

Interpretation: Written policies and procedures describe the process for verification of physician credentials. Ongoing periodic assessments of current physician license/other license/certification may be obtained from the state Licensing Board of Medicine or other Licensing/Certification Boards, or verification of physician privileges at the local or regional accredited hospital. The organization must have a mechanism to ensure that orders are only accepted from currently licensed physicians.

Evidence: Written Policies and Procedures  
Approved Physician List  
Response to Interviews
Standard 1704. Patients will have an assessment of need and plan of care.

Standard 1704, Criterion A: Written policies and procedures describe the process for assessment and the plan of care.

Interpretation: The Pharmacy Services program has written policies and procedures that describe the process for a patient assessment, the development of the plan of care and the frequency and the process for the plan of care review. The plan of care should be appropriate for the type of treatment/care that is provided. Care planning is directed toward driving positive patient outcomes.

Evidence: Written Policies and Procedures

Standard 1704, Criterion B: All patients referred for Pharmacy Services will have an assessment appropriate of therapy provided.

Interpretation: An assessment will be performed and information documented in the patient’s record for patients referred for pharmacy services. The assessment will focus on appropriateness for therapy in the home, appropriateness of medication to include dosing and frequency of dose, safety in the home, and method administering the drug to the patient.

Evidence: Patient Record Reviews

Standard 1704, Criterion C: There is a written plan of care for each patient accepted for services and based upon assessment data.

Interpretation: The plan of care will include at a minimum: (1) problems; (2) goals; (3) interventions; (4) monitoring parameters; and (5) patient outcomes.

Physician orders are needed to provide any services requiring the administration of medication, treatment(s), ongoing assessments or other activities as governed by state law. Physician orders may also be required under certain program requirements (i.e., Medicare, Medicaid, Managed Care, and other third party payers). The organization has a responsibility to obtain physician orders as applicable.

Evidence: Patient Record Reviews

Standard 1704, Criterion D: The organization will show evidence of the patient/caregiver participation in the plan of care.

Interpretation: The patient/responsible parties have a right to be involved in the development of the plan of care and any changes in that plan. However, the degree of involvement may vary depending on the ability of the patient to participate in the plan of care. At a minimum, the patient or responsible party must agree to the plan of care prior to the beginning of services and as subsequent changes occur.

The patient record must show involvement of the patient/family/caregiver in the development or at least agreement to the plan of care and any revisions made to the plan. The following are suggestions as to how organizations may document this information: (1) the plan of care may be signed by the patient/responsible party; (2) a notation may be made in the patient record that the patient/responsible party participated in the development of the plan of care; (3) there may be documentation in the patient
record that the plan of care was reviewed and accepted by the patient/responsible party; or (4) there is
evidence that the plan of care was provided to the patient for review and change.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1704, Criterion E: Pharmacy services are delivered in accordance with the written plan
of care.

Interpretation: The patient record reflects that pharmacy services are delivered in accordance with the
plan of care and directed at achievement of established goals.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1704, Criterion F: There is evidence that the plan of care is reviewed.

Interpretation: There is documentation in the patient record that reflects the plan of care is reviewed for:
(1) appropriateness (care being provided is still needed); (2) effectiveness (patient outcomes/response to
care); and (3) to determine if all needed services are being provided. Included in this review is a
discussion with the patient/responsible party to determine the level of satisfaction with the care that has
been provided. Notation of a review may be made in the patient record, in minutes of meetings, such as
team meetings, or case conferences.

The organization follows program policies and any applicable laws and rules for the frequency of plan
of care review. The plan of care should be reviewed: (1) at a minimum of every 60 days; (2) when there
are changes in patient’s response to therapy; (3) when physician orders change; (3) at the request of the
patient; and (4) as defined in the pharmacy’s policy and procedure. The plan of care review would
occur more frequently based on the patient’s need for changes.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1704, Criterion G: There is evidence of changes in the plan of care based on
reassessment data.

Interpretation: Changes are noted on the plan of care and/or in the progress notes based on patient
requests, patient’s condition, patient’s response to therapy, and when physician orders indicate changes.

There is evidence of communication to the physician regarding the patient’s condition. If new or revised
patient or treatment goals are indicated, they must be reflected in a revised plan of care. Revised plans of
care shall be approved by the patient’s physician.

Evidence: Patient Record Reviews

Standard 1705. Patient and/or caregiver education focus on goal and outcome achievement.
Standard 1705, Criterion A: Written policies and procedures describe the process for patient and/or caregiver education.

Interpretation: The Pharmacy services program has written policies and procedures that describe patient and/or caregiver education. The policies and procedures must include: (1) treatment and disease management education; (2) proper use, safety hazards, and infection control issues related to the use and maintenance of any equipment provided; (3) plan of care; (4) how to notify the company of problems, concerns and complaints; and (5) emergency preparedness information.

Evidence: Written Policies and Procedures

Standard 1705, Criterion B: Patient and/or caregiver education must focus on goal and outcome achievement as established in the plan of care.

Interpretation: Patient education is an integral part of pharmacy services. Assessment of the patient and/or caregiver’s knowledge deficits and learning abilities are evaluated during the initiation of services. Knowledge deficits and learning abilities are documented on the care plan or in the progress notes. Patient education/instruction will proceed in accordance with the patient’s willingness and ability to learn.

Education must be coordinated with the patient/caregivers and the health care team and must focus on goal and outcome achievement as established in the plan of care. Elements of patient education may include, but not be limited to: (1) ongoing assessment of patient and caregiver’s learning needs; (2) communication of needs to other health care team members; and (3) incorporating patient needs into the plan of care. The patient records will include documentation of all teaching, patient’s response to teaching, and the patient’s level of progress/achievement of goals/outcomes. Written instruction will be provided to the patient as appropriate.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1706. Pharmacy Services discharge patients as appropriate and in accordance with established policies and procedures.

Standard 1706, Criterion A: Pharmacy Services follow discharge policies and procedures.

Interpretation: The organization has a process, which assesses the patient’s ongoing appropriateness for therapy/services. The written discharge policy will define the activities that represent patient discharge.

The patient record should reflect discharge planning activities, the patient’s response and understanding to these activities, patient care instructions and a reasonable notice prior to discharge whenever possible.

There is a discharge summary report or notation in the progress notes or a software section dedicated to discharge that includes: (1) a summary of the services provided; (2) patient’s response to therapy, i.e. progress toward clinical goals; (3) the date and reason for the discharge; (4) a brief description of ongoing needs that could not be met; (5) any instructions or referral information given to the patient/responsible party. A copy of the discharge summary is made available to the physician and a copy is placed in the patient record.
Standard 1707. All pharmaceuticals, supplies, and equipment are dispensed/delivered/administered in accordance with applicable laws/regulations and organization policies and procedures.

Standard 1707, Criterion A: A Registered Pharmacist must review all patient medications and consult with other health care professionals caring for the patient, including the physician. All OBRA counseling is completed as specified by law.

Interpretation: A licensed pharmacist must review all prescription and non-prescription medications that a patient is currently taking prior to dispensing medications.

A medication profile is established at the start of therapy. This profile is updated and kept current minimally every 30 days, whenever there are changes in the patient's medication therapy, or as designated by the pharmacy policy and procedures. If patient is transferred to another healthcare facility, a copy of the medication profile is offered to the new facility or agency.

A licensed pharmacist is specifically responsible for recognizing the following as they pertain to infusion related diagnosis and infusion drugs: (1) side effects; (2) toxic effects; (3) allergic reactions; (4) desired effects; (5) unusual and unexpected effects; (6) drug interactions; (7) appropriateness of the drug for the patient's diagnosis; (8) appropriateness of the dose; (9) changes in the patient's condition that contraindicate continued use of the drug. The pharmacist, in conjunction with other health care professionals caring for the patient, must be able to anticipate those effects which may rapidly endanger a patient's life or well being, and instruct the patient, family member and/or caregiver, as necessary, in following the prescribed regimen.

Evidence: Patient Record Reviews
Written Policies and Procedures
Response to Interviews

Standard 1707, Criterion B: Medications and supplies are accurately labeled and dispensed to the patient for whom they are ordered. Labels of Compounded Sterile Preparations (CSPs) will include: (1) names and amounts or concentrations of ingredients; (2) total volume; (3) the Beyond Use Date (BUD); (4) route of administration; (5) storage conditions; (6) instructions for use; and (7) any additional requirements specified by the individual state Board of Pharmacy for labeling.

Interpretation: Medications dispensed to patients are appropriately labeled according to applicable law and regulation and standards of practice. In the absence of sterility testing, Beyond Use Dating follows USP General Chapter <797> requirements.

Evidence: Pharmacy Logs
Prescription Labels
Delivery Tickets or Logs
Standard 1707, Criterion C: There are written policies and procedures relating to special education, experience, or certification requirements for pharmacy staff to prepare compounded sterile preparations.

Interpretation: The organization must have written guidelines defining any special education, experience or certificates necessary for pharmacy staff to prepare sterile compounded preparation. Qualifications may vary based upon classifications of drugs as well as State Board of Pharmacy requirements, and requirements defined by USP General Chapter <797>.

For organizations that prepare compounded sterile preparations (CSPs), compounding personnel training is documented initially during orientation and at a minimum annually. Initial training and review may include multi-media instructional sources and professional publications. Training must address: (1) the principals and practical skills of aseptic technique; (2) hand hygiene and garbing procedures; and (3) maintenance of the controlled air environment(s). Compounding personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially and at least annually or semi-annually thereafter as dictated by risk level of compounded sterile preparations.

Evidence: Written Policies and Procedures
Personnel Record Review

Standard 1707, Criterion D: There are written policies and procedures that address response to adverse drug reactions.

Interpretation: The organization has written policies and procedures that address the steps taken if an adverse drug reaction occurs.

Policies and procedures should address the standard protocol for managing and reporting Adverse Drug Reactions (ADR) internally and to outside state agencies as required by law. This may include standing orders to treat anaphylaxis and recommended dosages of drug per age group.

Evidence: Written Policies and Procedures
Response to Interviews
ADR Record Book
MedWatch Records (for more information see www.fda.gov/medwatch)

Standard 1707, Criterion E: There are written policies and procedures to ensure that the right patient receives the right treatment.

Interpretation: There is a process to verify the identity of the patient and the treatment the patient is to receive.

Evidence: Written Policies and Procedures
Response to Interviews
Patient Records

Standard 1708. The pharmacy has a system for the recall of medications and products.
Standard 1708, Criterion A: The organization has written policies and procedures for medication and product recall.

Interpretation: There are written policies and procedures for tracking medications and products dispensed to patients. There are written procedures for external reporting of medication or product defects. There are written procedures for the safe disposition of recalled medications or products dispensed to patients.

Evidence: Written Policies and Procedures  
MedWatch Records (for more information see www.fda.gov/medwatch)

Standard 1708, Criterion B: Records are maintained to identify each patient who is receiving or has received recalled medications or products.

Interpretation: Documentation will include, but not be limited to, the manufacturer of each patient’s medication, lot numbers and expiration dates. Serial numbers will be used to track equipment.

Evidence: Dispensing/Recall Records  
Equipment tracking logs  
Patient Record Reviews  
Response to Interviews

Standard 1708, Criterion C: Staff implements organization’s policies and procedures for the safe disposition of recalled medications or products and external reporting.

Interpretation: Staff implements the organization’s written policies and procedures for the safe disposition of recalled medications or products stocked and dispensed to patients. Staff implements the organization’s written policies and procedures for external reporting of medication or product defects. Patient’s physicians are notified when medications or products are recalled.

Evidence: Dispensing/Recall Records  
Patient Record Reviews  
Response to Interviews  
MedWatch records

Standard 1709. All compounded sterile preparations are prepared by qualified personnel in a suitable environment using appropriate aseptic technique.

This standard and criterions only apply if the organization performs sterile compounding.

Standard 1709, Criterion A: The organization has written policies and procedures for compounded sterile products, and must minimally comply with all requirements set forth by USP General Chapter <797> and the requirements set forth by individual state boards of pharmacy.

Interpretation: The written policies and procedures for compounded sterile products defines quality control procedures for monitoring aseptic technique and the compounding environment to comply with established standards by the individual Board of Pharmacy regulations and Federal law. The written
policies and procedures define processes for preparing/compounding sterile products and include: (1) environmental considerations of security, temperature, and ventilation; (2) introduction of medications and supplies into the controlled air environments (3) appropriate hand hygiene and garbing procedures; (4) proper aseptic technique and manipulations within the ISO Class 5 environment to include: (A) procedure for media-fill process validation; (B) preparation of parenteral drugs for administration in various delivery devices, i.e., elastomerics, ambulatory pump reservoirs, minibags, LVP, etc; (C) procedure for use, calibration, maintenance, and accuracy testing of automated compounding devices (ACD); (D) preparation of sterile drugs from non-sterile products, if applicable; (E) procedure for pyrogen and endotoxin testing, if applicable; and (F) procedure for hazardous drug preparation, if applicable.

Evidence: Written Policies and Procedures
Observation of compounding processes
Media Fill Logs
Pyrogen/Endotoxin testing logs
Compounding equipment calibration testing and accuracy testing logs

Standard 1709, Criterion B: The organization has written policies and procedures for cleaning and disinfecting of the controlled air environment(s).

Interpretations: Cleaning and disinfection procedures will follow requirements set forth by USP General Chapter <797> and the individual state Boards of Pharmacy. Written policies and procedures for cleaning of the controlled air environments, i.e., ISO Class 5 area(s), ISO Class 7 or better clean room, and ISO Class 8 or better anteroom, to reduce the risk of particulate matter in the work area and contamination of the compounding environment include: (1) process and frequency for cleaning work surfaces, equipment, and work areas, i.e., floors, walls, ceilings, counters, etc; (2) using dedicated cleaning tools specific to the area, including the use of non-shedding wipers, sponges, and mops; (3) use of appropriate disinfectant solutions; and (4) documentation of the cleaning process.

Evidence: Written Policies and Procedures
Quality Control Records

Standard 1709, Criterion C: Qualified personnel comply with aseptic technique when compounding sterile preparations.

Interpretation: Personnel demonstrate knowledge and understanding of contamination control and aseptic techniques in accordance with written policies and procedures, USP General Chapter <797>, state specific Board of Pharmacy regulations and Federal law. Personnel qualifications include initial and follow-up training for periodic evaluation of performance.

Evidence: Observation
Quality Control Records
Personnel Record Review
Response to Interviews

Standard 1709, Criterion D: Non-hazardous compounded sterile preparations are compounded in an ISO Class 5 or better primary engineering control, such as an ISO Class 5 or better room, ISO Class 5 or better countertop area; ISO Class 5 or better laminar airflow workbench (LAFW), ISO Class 5 or better Biological Safety Cabinet (BSC) or an ISO Class 5 or better Compounding Aseptic Isolator (CAI). The ISO Class 5 or better primary engineering control is located within an
ISO Class 7 or better room. For clean rooms providing a physical separation from the anteroom, a minimum positive pressure differential of 0.02-0.05 - inch water column is required. The only exception would be an ISO Class 5 or better CAI with documentation from the manufacturer that the CAI does not need to be used within an ISO Class 7 or better environment.

Interpretation: The ISO Class 5 and ISO Class 7 environment are certified every 6 months or in accordance with ISO 14644 standards, NSF 49, state Board of Pharmacy regulations, USP General Chapter <797> and/or Federal law. A qualified independent contractor performs certification according to accepted standards for operational efficiency to include but not limited to: viable and non-viable particle levels, air changes per hour (ACH), and pressure differential monitoring. Procedures are maintained for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines.

Evidence: Observation
   Engineering Control Certification Reports and Certification Certificates
   Quality Control Records
   Response to Interviews

Standard 1709, Criterion E: Hazardous compounded sterile preparations are compounded in an ISO Class 5 or better Biologic Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI). The ISO Class 5 or better BSC or CACI is placed in an ISO Class 7 or better area that is physically separated and has not less than 0.01-inch water column negative pressure to the adjacent ISO Class 7 or better anteroom. In facilities that prepare a low volume of hazardous drugs, a negative pressure room is not required.

Interpretation: The ISO Class 5 BSC/CACI and ISO Class 7 environment are certified every 6 months or in accordance with ISO 14644 standards, NSF 49, state Board of Pharmacy regulations, USP General Chapter <797> and/or Federal law. A qualified independent contractor performs certification according to accepted standards for operational efficiency to include but not limited to: viable and non-viable particle levels, air changes per hour (ACH), and pressure differential monitoring. Procedures are maintained for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines.

Evidence: Observation
   Engineering Control Certification Reports and Certification Certificates
   Quality Control Records
   Response to Interviews

Standard 1710. The pharmacy assures pharmaceuticals are stored under appropriate conditions.

Standard 1710, Criterion A: There are written policies and procedures relating to pharmaceutical storage.

Interpretation: The written policies and procedures must include, but are not limited to: (1) Storage of pharmaceuticals (separated from food items or other sources of contamination); (2) monitoring of storage room, refrigerator, and freezer temperatures; (3) accessibility of legend drugs; (4) storage during delivery; (5) cleaning and disinfecting of any reusable containers (i.e. delivery coolers); and (6) pharmaceutical labeling as to the appropriate storage...
Evidence: Written Policies and Procedures
Temperature logs
Cleaning logs
Observation

**Standard 1710, Criterion B:** The pharmacy stores pharmaceuticals under appropriate conditions of security, sanitation, light and temperature.

Interpretation: Pharmaceuticals are stored in accordance with manufacturer or USP requirements. Temperatures are monitored wherever pharmaceuticals are stored to assure the requirements are met. Prescription and legend drugs are stored in the licensed pharmacy, which is accessible only under the supervision of licensed pharmacist(s).

Evidence: Observation
Temperature logs

**Standard 1710, Criterion C:** The pharmacy uses delivery containers that assure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

Interpretation: The pharmacy assures pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperatures in the course of deliveries. Where appropriate, the pharmacy uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with manufacturer and USP <797> requirements.

The policies and procedures for the cleaning and disinfecting of any reusable containers are implemented. Shipping methods are tested periodically to ensure that containers stay within specified temperature requirements.

Evidence: Observation
Shipping Records

**Standard 1710, Criterion D:** The pharmacy ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light and temperature in the patient’s home.

Interpretation: The pharmacy has and acts upon information affecting the maintenance of appropriate conditions of sanitation, light and temperature in the patient’s home. Where necessary, the pharmacist intervenes appropriately to ensure that appropriate conditions are achieved or maintained. Pharmaceuticals dispensed to the patient are clearly labeled as to the appropriate storage.

Evidence: Prescription Labeling
Response to Interviews

**Standard 1711.** Nutritional products are stored and provided in accordance with organization policies and procedures and applicable law and regulations.
This standard does not apply to organizations that either does not provide enteral nutritional products or products are provided through the DME service model.

Standard 1711, Criterion A: The Pharmacy has written policies and procedures for the provision of enteral nutritional products.

Interpretation: The pharmacy has written policies and procedures for the provision of enteral nutritional products. The written policies and procedures must include, but are not limited to: (1) storage of products; (2) rotation of products; (3) labeling of products; (4) tracking of lot number and expiration dates; (5) disposal/return of expired products; and (6) written instructions the patient will receive.

Evidence: Written Policies and Procedures

Standard 1711, Criterion B: Enteral nutritional products are stored in accordance with policies and procedure and manufacturer guidelines.

Interpretation: The pharmacy ensures that enteral products are stored in an appropriate environment. The storage room temperature is monitored to verify compliance with manufacturer guidelines for storage.

Evidence: Written Policies and Procedures
Temperature Logs
Response to Interviews

Standard 1712. The pharmacy maintains medical equipment.

Standard 1712, Criterion A: The pharmacy has policies and procedures relating to the maintenance and repair of medical equipment.

Interpretation: The written polices and procedures must include, but are not limited to: (1) cleaning, storage, and transportation of patient-ready equipment; (2) separation of dirty and clean equipment; (3) warehousing and tagging equipment; (4) use of cleaning and disinfecting agents and process of contaminated or soiled home medical equipment, including curbside disinfection; (5) maintenance and repair of equipment; (6) separation of inoperative equipment; (7) tracking of equipment; (8) manufacturer recalls; and (9) back-up systems for equipment or power failure. Written polices and procedures will clearly define training, qualifications, and skill validation required by personnel to perform routine maintenance and repair of all equipment. Written policies and procedures clearly define the use of outside repair sources.

Evidence: Written Policies and Procedures

Standard 1712, Criterion B: Pharmacy staff is trained to perform routine cleaning and maintenance of equipment.

Interpretation: Staff responsible for delivery; set-up; pick-up and maintenance of equipment are trained and competent in the use of all equipment.

Evidence: Personnel training records
Standard 1712, Criterion C: Pharmacy staff implements the organization’s written policies and procedures for the delivery, set-up, environmental requirements, and electrical safety of equipment dispensed to a patient.

Interpretation: Pharmacy staff will perform environmental assessments, set-up, and provide appropriate information regarding safe and proper use of all equipment according to manufacturer’s guidelines.

Prior to or at time of delivery, personnel will address at a minimum the following: (1) safety and adequacy of electrical outlets (if applicable); (2) safe use of extension cords and outlet adapters (if applicable); (3) location and function of all equipment controls; and (4) expected results/outcomes of proper use.

Training provided to the patient will be documented in the patient record according to the company’s written policy and procedure.

Equipment used in patient care is properly cleaned and maintained. Routine maintenance, preventive maintenance, and repairs will be performed according to manufacturer’s guidelines. Equipment requiring calibration will be calibrated according to manufacturer’s guidelines. Inoperative equipment must be separated from other equipment and tagged for repair.

Evidence: Maintenance logs
Manufacturer’s service manuals/set-up guidelines
Patient Records-including documentation of pump setting verification
Response to Interviews

Standard 1713. The pharmacy will have access to a reference library appropriate to the level of the services provided.

Standard 1713, Criterion A: The Pharmacy staff will have access to a reference library appropriate to the level of services provided.

Interpretation: The pharmacy staff will have access to a reference library appropriate to the level of services provided. The pharmacy has available reference books, journals, Internet access, etc. appropriate for the patient population served. The library will contain, at a minimum: (1) drug compatibility and stability; (2) drug interactions; (3) general clinical references; (4) Pharmaceutical Compounding - Sterile Preparations and (5) pharmacy regulations for any state into which medications are dispensed.

Evidence: Observation
Response to Interviews
SECTION 1800: AMBULATORY INFUSION CENTER

SCOPE OF SERVICES

In addition to all 1700 pharmacy standards, the following standard(s) and criteria apply to Ambulatory Infusion Center Programs.

Standard 1801. The facility housing the Ambulatory Infusion Center will be staffed by qualified health care providers in accordance with state laws, regulations and recognized professional practice standards.

Standard 1801, Criterion A: The Ambulatory Infusion Center services will be provided by qualified personnel and administered in accordance with the organization's policies and procedures, federal, state and local laws and established regulatory guidelines. The Ambulatory Infusion Center will meet laws/regulations for facilities that provide services/care to patients on site.

Interpretation: The Ambulatory Infusion Center will meet all guidelines specified by law or regulation relating to the facility, pharmacy and nursing, including but not limited to: (1) OSHA; (2) Federal, State, and local laws; (3) Fire department regulations; (4) Americans with Disabilities Act and (5) National Fire Protection Agency and Life Safety Code

Evidence: Observation
Inspection Reports
Response to Interviews

Standard 1801, Criterion B: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required in the facility and its use.

Interpretation: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The resuscitation equipment/supplies required shall include but not be limited to: (1) resuscitation bag and mask, (2) medications for adverse reaction and/or resuscitation with protocols for use and (3) current CPR posters.

Evidence: Written Policies and Procedures
Medication Protocols

Standard 1801, Criterion C: The Ambulatory Infusion Center implements its policies and procedures for resuscitation equipment/supplies.

Interpretation: The Ambulatory Infusion Center implements the written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The facility educates the professional staff members in the use of resuscitative equipment/supplies on at least an annual basis. The cart(s) and/or box(s) that store the resuscitative equipment/supplies are inventoried on a regular basis at least every 30 days to insure correct inventory and non-expired products.
Standard 1801, Criterion D: The Ambulatory Infusion Center has written policies and procedures that describe patient monitoring during infusion.

Interpretation: The Ambulatory Infusion Center has written policies and procedures that describe the monitoring of patients during infusion by either a pharmacist or nurse or both. The written policies and procedures describe the equipment required for monitoring. The monitoring equipment must be visual and audio to warn staff when no one is in the room with the patient.

Evidence: Written Policies and Procedures

Standard 1801, Criterion E: The Ambulatory Infusion Center implements its policies and procedures for patient monitoring during infusion.

Interpretation: The Ambulatory Infusion Center implements the written policies and procedures that describe the monitoring of patients during infusion. The facility educates the professional staff members in the use of monitoring equipment on at least an annual basis. The monitoring equipment is calibrated and preventative maintenance is performed per manufacture guidelines.

Evidence: Observation
In-service Education Files/Logs
Inspection/Calibration/Maintenance Logs
Response to Interviews

Standard 1801, Criterion F: The Ambulatory Infusion Center has adequate space and climate controls for treating patients on site.

Interpretation: The site has adequate space for supplies, equipment, waiting area and treatment areas. The facility has separate treatment areas. Ventilation is adequate to maintain comfortable temperature and humidity levels.

Evidence: Observation
Response to Interviews
ACCREDITATION
POLICIES & PROCEDURES
Accreditation Policies & Procedures

I. Introduction

The Accreditation Commission for Health Care, Inc. (ACHC) is an independent, 501(c)3 non-profit accrediting organization, which is certified to ISO 9001:2008 standards. ACHC is governed by a voluntary Board of Commissioners (Board), which is composed of health care professionals and consumers. The Board is responsible for leadership, governance and oversight of the quality of all services provided by the organization. The Board focuses on the development and maintenance of services that promote excellent outcomes through national health care standards. The Board accepts the ongoing duty to monitor the mission and philosophy of the organization and establish the future direction of ACHC in keeping with its mission. In addition to the expert Board members, the organization solicits the support and input from leadership committees such as the Standards and Review Committee, as well as clinical advisors.

The policies and procedures contained in this section pertain to all applicant organizations, whether they are applying for the first time, renewing, or adding or eliminating branches or services. All applicant organizations must follow these accreditation policies and procedures to achieve ACHC accreditation and maintain compliance. Submission of a signed application and contract for survey by an applicant organization constitutes intent to adhere to the policies and procedures in effect on the date on which the application is received by ACHC.

II. Eligibility

Applicant organizations which provide health care services and/or products may apply for accreditation if all of the following eligibility criteria are met:

A. Must be currently operating within the United States and/or its territories;
B. Must have served a minimum of ten (10) clients/patients and have (7) active clients/patients at the time of the survey;
C. Is licensed according to applicable state and federal laws and regulations and maintains all current legal authorization to operate;
D. The building in which services are provided/coordinate is identified, constructed, and equipped to support such services;
E. Clearly defines the services it provides under contract or directly;
F. Must be willing to complete and sign attestation to never falsify or misrepresent accredited programs;
G. Must submit all required documents and fees to ACHC within specified time frames;
H. Medicare providers must meet all criteria for participation with Medicare.

Deemed Status Eligibility

Currently, deemed status accreditation is available to home health and DMEPOS applicant organizations. In addition to the above eligibility criteria, applicant organizations applying for deemed status must meet the following requirements:

A. Meet the intent of the definition set forth by Medicare.
B. Meet the intent of the regulations set forth by state and/or federal regulations for certification;
C. Application must clearly denote and/or include:
   - the intent to seek deemed status
   - copy of CMS-855 approval letter (new providers/organizations only)
   - evidence of successfully completed OASIS transmission (Home Health only)
ACHC Programs

ACHC provides programs with designated services for accreditation. The applicant is required to accredit all services provided within that corporate structure. If the applicant organization offers services under another corporate name/structure and the services are covered under an additional ACHC program, the organization has the option to add additional services for accreditation.

(1) **Private Duty Aide:** Aide services encompass all levels of care provided by a nursing assistant or sitter including Personal Care Services, chore, companion sitters and homemakers.

(2) **Private Duty Nursing:** PDN services are usually provided either hourly or by shift and are covered by various payers, but not Medicare. Services can be provided by an RN or LPN.

(3) **Home Health:** Home Health services are skilled services that are usually provided on a visit basis, as opposed to hourly, for a short duration of time. These services are usually provided by a licensed and/or Medicare certified agency. Home Health services are provided by skilled professionals including nursing; physical, occupational and speech therapy; medical social work and home health aide.

(4) **Home/Durable Medical Equipment:** HME/DME services are the selection, delivery, set-up and maintenance of medical equipment and/or oxygen as well as patient education regarding the use of this equipment. Assessment and hands-on care of patients, including performance of any tests, is considered clinical services and will be accredited using the Clinical Respiratory Standards. This includes pulse oximetry measurements.

(5) **Clinical Respiratory Care:** This service is provided by a licensed respiratory care practitioner or respiratory therapist. The care includes the skilled assessment, treatment and education of patients.

(6) **Hospice:** Hospice is the care of patients with life limiting illnesses in the home or hospice inpatient facility. End of life care involves a multidisciplinary approach to medical care, pain management and emotional/spiritual care. This team approach will be used in the survey process. ACHC surveys are conducted by a hospice nurse surveyor as well as a clinical support surveyor, such as a medical social worker. An agency that provides inpatient services must adhere to the inpatient standards as well as the primary hospice standards.

(7) **Infusion Nursing:** This service is the administration of parenteral medications via various accesses and ports by an RN specifically trained in these specialized services. This service can be provided in a variety of settings.

(8) **Medical Supply Provider:** The storage and delivery of medical supplies designed to meet the needs of a client/patient requiring the product for their medical management in the home care setting. A physician generally prescribes these services. The items sold are usually disposable or semi-durable in nature. The supplies are normally delivered by mail.

(9) **Pharmacy Services:** The infusion therapy continuum of care includes IV drug mixture preparation, IV administration, therapy monitoring, client/patient counseling and education. It is the administration of medications using intravenous, subcutaneous and epidural routes. The IV therapies include IV antibiotics, prescribed primarily for diagnoses such as osteomyelitis, sepsis, cellulites, total parenteral nutrition, pneumonia, sexually transmitted diseases and others. ACHC scope of service includes: home infusion pharmacy, specialty pharmacy, first
dose services, ambulatory infusion centers and respiratory nebulizer medications.

(10) **Complex Rehab and Assistive Technology Supplier:** Rehabilitation Technology Supplier Services are defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental control, augmented communication and other equipment and services that assist the person in performing their activities of daily living.

(11) **Fitter Services:** These services include prosthetic fitting of a variety of products such as diabetic shoes and post-mastectomy breast prosthesis.

(12) **Sleep Lab:** A Sleep Lab is a facility that provides testing for sleeping disorders either in an Independent Diagnostic Testing Facility (IDTF), as defined by CMS, or in hospital based testing facilities. Sleep testing can also be conducted in the home.

### III. Purpose or Principles Governing the Accreditation Survey

#### A. Compliance

Throughout the survey process, ACHC determines whether the organization is meeting the intent of the accreditation standards. Proof of compliance is based upon such things as review of client records, personnel records, policies and procedures, as well as onsite observations and interviews and other activities as necessary.

**Standard Revision Compliance**

It is the organization's responsibility to ensure compliance with ACHC standards at all times during the accreditation period. Upon revision of standards, ACHC will establish timeframes for the organization to come into compliance. Timeframes for compliance are determined in part by mandatory timeframes required by state/federal regulations, HIPAA, etc. Compliance with revised standards will be 120 days after notification of the revision by ACHC.

#### B. Education

While the organization is preparing for its onsite survey, ACHC is available to provide assistance in interpretation of standards. A list of independent consultants is available for organizations that need more extensive assistance with preparation for accreditation. These consultants are not employees of ACHC and use of any consultant does not guarantee successfully becoming accredited. ACHC does not endorse any consultant(s). During the onsite survey, surveyors will provide education in areas where standards are not fully met, in addition to "best practice" suggestions to help the organization achieve optimum performance.

#### C. Frequency of Surveys

Accreditation surveys are conducted upon receipt of a new accreditation application and, after receipt of accreditation status, on a triennial basis (upon receipt of a renewal application). All surveys are unannounced. Organizations are allowed to choose up to 10 black out days on which ACHC will not schedule a survey. ACHC does not conduct surveys on major holidays including New Years Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the day after Thanksgiving, Christmas Eve, and Christmas Day.
Intermittent unannounced surveys are conducted based upon original survey results, random selection of a percentage of accredited organizations, number of branch additions during an accreditation period, or if a grievance/complaint has been received against an accredited organization.

D. Types of Surveys

1. **Initial Survey**: Organizations which apply for ACHC accreditation for the first time will have an initial survey. Applicant organizations must have served at least ten (10) active clients/patients prior to application submission and have seven (7) clients/patients on service at the time of survey.

2. **Renewal Survey**: Organizations that are accredited by ACHC will receive notification regarding renewal of their accreditation 12 to 15 months prior to their expiration date. Renewal surveys are processed in the same format as an initial survey; however, during the site survey the surveyor also reviews previous deficiencies for compliance.

3. **Deferral Focus Survey**: Organizations that receive a deferral decision may require a focus survey at the applicant organization’s expense. A deferral decision requires a plan of correction and evidence demonstrating compliance with the standard(s) in question. A focus survey will be scheduled if a review of personnel or client/patient files, or site observations are required to verify results of the plan of correction.

4. **Interim Survey**: ACHC reserves the right to randomly visit any ACHC accredited organization during the three-year cycle to determine ongoing and continuing compliance with standards. These interim surveys are random and unannounced. If significant non-compliance with standards is found that requires further action from ACHC, the costs of the survey will be billed to the organization.

5. **Service Addition Survey**: Organizations adding a service(s) within their accredited program during their three-year accreditation period must notify ACHC of the addition within 30 days and complete a Service Addition Application. Service addition applications follow the same process and survey procedures as Initial and Renewal applications. All service additions require an onsite survey to ensure compliance of added service scope standards. Organizations requesting a deemed status survey must have all documentation regarding licensure and certification from CMS/State Agency before ACHC can conduct a survey. (See Section VI. D. Service Addition and Section VII. A. Advertising)

6. **Branch Addition Survey**: Organizations adding branches that meet ACHC’s branch definition must notify ACHC at least 30 days prior to the opening of that branch, complete a Branch Addition Application for each branch added, and submit required information and applicable branch fees. To qualify as a branch addition, the branch must provide the same services under the organization’s current accreditation. Branch additions may require an onsite survey based on the number of sites seen during the initial accreditation survey. Organizations requesting deemed status must have all documentation regarding licensure/certification from CMS/State Agency before ACHC can conduct an onsite survey. ACHC branch surveys consist of a desk review of submitted documentation and photos, and, when necessary, onsite surveys. (See Section VI. C. Branch Office Addition and Section VII. A Advertising)
IV. Accreditation/Survey Process

A. Interpretive Guide

Prospective applicant organizations can receive an ACHC Interpretive Guide by registering the organization on the ACHC website and downloading a free copy of the Interpretive Guide. ACHC, working with the applicant organization, determines which accreditation manual is most appropriate for services provided. (See Section II. ACHC Programs for guidelines regarding selection of programs and services). Once the manual is ordered, the company will be assigned an Account Manager that will be available to assist them with any questions. Also a username and password will be assigned and the customer will have access to our customer central website. Customer central is a private website that will contain all the information to get started on your accreditation. It will have the application, interpretive guide (standards) and PER specific to the services the customer provides.

B. Organizational Structure and Governance

Based on governance, complexity of corporate structure, tax reporting, and other factors, ACHC will determine the number of applications and number of surveys required. Organizations are required to submit statistical data forms for all locations and an organizational chart with the application to assist in the determination of corporate structure.

C. What is Required to Submit to ACHC to Start the Accreditation Process

Application:

Applications are located on customer central which is an aspect of the ACHC accreditation manual. All information submitted and/or reviewed by ACHC is regarded as confidential and in compliance with HIPAA regulations.

Applications must be filled out correctly and completely in order to proceed with the accreditation process. Statistical data forms are located in the application and must be filled out for the corporate location and all branches (if necessary). Please direct any questions about filling out your application with your account manager. All tax ID; NPI, MCR provider #'s and/or NSC #'s must be included on the application.

Upon receipt of an application, ACHC will assign an application number.

Once application process is complete and validated by ACHC, the onsite survey will be completed within 9 months. If an onsite survey is not completed within 9 months of the application receipt date, by fault of the applicant organization, the application expires and ACHC will require a new application and accreditation fees if the applicant organization wishes to continue the accreditation process.

Deposit:
A deposit of $1500.00 is required to be sent in with your application and PER. Deposits are non-refundable and are applied to your accreditation fees.

D. Preliminary Evidence Report (PER)

The PER is included on customer central as part of the accreditation manual and must be returned with the completed application and deposit. ACHC staff will be available to answer questions during the PER completion process. PER’s can be completed electronically or by paper (Electronically is preferred). Organizations with 10 or more locations must submit their PER in electronic format. After ACHC receives the customer’s PER(s), accreditation staff prepares and mails a complete PER package to each member of the survey team.

***Note: If one of the three items (application, deposit, PER) is not submitted to your account manager, a contract for survey will not be generated until we have everything in its entirety. Once all three items are submitted to ACHC, this is indication that your organization is ready for an ACHC survey.

E. Accreditation Fees

As part of the application review process, a quote for accreditation fees is prepared. Fees, number of surveyors/type of surveyors and number of survey days are based upon statistics from the organization’s last completed fiscal year prior to application for those program(s)/service(s) indicated on the Application and Statistical Data Form. Relevant statistics include but may not be limited to: (a) number and type of services; (b) number of employees; (c) volume of clients/patients served; and (d) number of branches. Applicant organizations which have not completed at least one fiscal year prior to application must submit year to date statistics.

Full accreditation fees are not refundable. Requests for partial refunds must be made in writing, detailing the reason for the request. The partial refund amount is determined on an individual basis and is dependent on the stage in the accreditation process where the organization has withdrawn it’s application.

The applicant organization is held accountable for accurate and timely information. ACHC reserves the right to review and/or adjust accreditation fees based on new or validated information obtained during the survey process which may affect the number of survey days or surveyors required. Continuation of the survey process is contingent upon receipt of total fees prior to the survey. If a surveyor arrives at an organization for survey and discovers the organization is providing services that were not indicated on its’ application, the surveyor will notify ACHC and the organization will be responsible for any additional survey fees.

Accreditation fee structures are reviewed periodically. ACHC reserves the right to adjust accreditation fees and establish the effective date of change based upon the review.

F. Contract for Survey

Once fees and payment schedules are confirmed with the applicant organization, a Contract for Survey is issued. The Contract for Accreditation Survey identifies, but is not limited to: (1) payment schedule for accreditation fees; (2) rescheduling provisions; (3) contract execution timeframe; and (4) notification time frames for organizational changes in ownership/governance, facilities, services, etc.
The organization must review the contract in its entirety and sign and return the entire contract to ACHC within seven (7) calendar days to ensure continuation of the accreditation process. Failure to meet any of the contract terms may result in cancellation of the survey with rescheduling/cancellation fees assessed.

G. Scheduling

Upon execution of the contract, the survey is scheduled. Surveyors are chosen based on their qualifications in a specific area. The number of surveyors for a survey is determined by the size of the organization and the number of services provided. A minimum of one surveyor will be scheduled for all programs. A minimum of two surveyors, one nursing and one non-nursing surveyor (MSW or Clergy) will be scheduled for hospice program surveys. Additional surveyors are assigned based on the service(s) provided that is indicated on the application. Surveyors assigned will be discipline specific to the service(s) provided, which may result in a team of surveyors.

ACHC reserves the right to send a surveyor trainee as part of the survey team. Trainees are sent at no charge to the organization.

All ACHC surveyors/trainee’s must disclose any potential conflict of interest with the applicant organization to ACHC before the surveyor is assigned to conduct the survey. Surveyors/trainee’s with a confirmed conflict are not utilized for the survey being scheduled. Surveys are usually conducted 3 to 7 months after the application process has been completed and validated.

H. PER Review

After the survey is scheduled, the surveyor that has been selected to complete your survey will receive the application and PER that you submitted to your account manager. They will review your polices and all the information about your company. They will complete a desk review, which is a summary of any standards that may need to be corrected before he/she comes on site. This gives you as the provider a chance to make any changes up front to be compliant with ACHC’s standards.

You will receive the desk review at least 30 days prior the survey and you will be required to submit those changes back to your account manager. If your surveyor does not find any deficiencies in your PER review, you will be notified by your account manager and a survey can take place at anytime beyond that point.

I. Survey

Surveys are conducted by a single surveyor or a team of surveyors. Surveyors are selected based on the services being surveyed.

Entrance Conference

The surveyor(s) will conduct an entrance and exit conference with representatives of the organization. At the entrance conference, the lead surveyor will briefly introduce himself/herself, along with other members of the survey team (if applicable), discuss PER issues and tentative schedule, and answer questions regarding the survey.

Data Collection

The survey focuses on personnel files, client/patient records, financial management, service contracts, risk management, quality improvement activities, policies and procedures, onsite observations, operational and service delivery outcomes, and staff and client/patient interviews. All
applicants will be given explanation of findings/deficiencies throughout the survey process and again during the exit conference.

The applicant organization authorizes ACHC and/or its designated agents to access all records (including client/patient, personnel, financial management, risk management, utilization review, quality assurance and quality improvement) that are necessary to ascertain the degree of compliance with ACHC Standards. ACHC complies with all HIPAA, privacy and security regulations.

Exit Conference

During the exit conference, the surveyor(s) will discuss survey findings. While organization personnel are given the opportunity throughout the survey to provide information that does not appear readily available to the surveyor, the exit conference provides representatives of the organization a final opportunity to clarify information or present data that may not have been available to the surveyor during the survey. A final Summary of Findings will be sent to the organization that will include all details from the survey.

The surveyor does not render judgment as to whether the organization will be granted accreditation; rather, he/she may make a recommendation, based on observation, as to the organization's accreditation status. Her/his role is to review information presented and to clarify, observe, and verify data that supports compliance with applicable standards.

V. Accreditation Decision

A. Scoring

The lead surveyor ensures that all data collection tools and documentation are completed and submitted to ACHC for the scoring and document review process. Upon receipt of survey documentation ACHC staff reviews documentation for completeness and data is entered into the appropriate scoring tool for computation of survey scores.

B. Document Review

Accreditation staff reviews documentation and scoring and prepares a draft of the applicant organization's final written report (Summary of Findings) for review and final determination of status. The Summary of Findings indicates a finding of Met, Partially Met, Not Met or Not Applicable, to indicate the results of the data collected for each standard surveyed. Standards with findings of Not Met, Partially Met include a comment and recommendation to assist the organization in taking corrective action to meet the standard. A plan of correction (POC) is required for all standards that are not fully met.

The Senior Vice President of Clinical Compliance and Accreditation is responsible for review of accreditation results. The Standards and Review Committee (SRC) is responsible for oversight of the accreditation approval process. The SRC establishes guidelines for processing, scoring, reviewing, status determination and reporting results of accreditation applications. The Board of Commissioners reserves the right to make the final decision on all applications.

C. Accreditation Status Criteria

Approval of Accreditation
Full accreditation is awarded to an organization when the overall score and each section score are within a range of 90% or above. Submission of a plan of correction will be required for any standard not fully met. Accreditation is good for 3 years. Effective accreditation dates for new and renewal organizations are determined as follows:

New organization:
1. First day following the survey, if the organization passes survey on the first review.
2. First day after receipt of plan of correction once the plan of correction is approved from deferral status.
3. First day after the focus survey, if the deferral is cleared upon review.

Renewal organization:
1. First day following current accreditation expiration date if the organization passes survey on the first review.
2. First day following current accreditation expiration once the plan of correction is approved from deferral status.

Deferral of Accreditation

Deferral accreditation is given to an organization when the overall score is within the deferral range (80% up to 89.99%). Any individual section that scores below 90% or failure to meet any one Medicare Condition of Participation will also put the organization in deferral status. The organization is advised of the decision in writing and accreditation will be deferred pending submission of a plan of correction within 30 days and corrective documentation within 90 days of the date of ACHC’s notification letter. Once all documentation has been received and reviewed, a determination of the need for an onsite survey will be made.

Deferral focus surveys are invoiced at a per-surveyor per-day fee. After the focus survey takes place, if the organization is subsequently found to be in compliance and has a passing score in accordance with approval criteria, full accreditation is awarded and a Certificate of Accreditation will be issued.

If a focus survey is not required, based on the review of the plan of correction and corrective documentation, ACHC will determine which deficiencies are cleared and make a final decision regarding accreditation status.

Denial of Accreditation

Denial of accreditation is given to an organization when the total overall score is below 80%. If a determination is made to deny accreditation, the organization is advised in writing.

When accreditation is denied, new applicant organization has the option of reapplying for accreditation at any time they feel they are ready for survey. At the time of re-application, a new application must be submitted with appropriate application fee. Reapplications are processed and accreditation fees charged in accordance with the application process. Organizations that are denied as a result of a reaccreditation survey will be handled on a case by case basis. The organization will be responsible for full payment of the reaccreditation survey before that survey is scheduled.
D. Accreditation Documentation

All documentation regarding the provider’s accreditation is described in the approval letter which is sent with the Certificate(s) of Accreditation and signed by the Senior Vice President of Clinical Compliance and Accreditation. Certificates of Accreditation are provided for all locations listed in the Application for Accreditation and included in the survey process.

Organizations will be notified in writing of the accreditation decision within four weeks of the last day of the survey. Accreditation survey scores are not sent with the decision letter.

When applicable, the accredited organization should send a copy of the Letter of Accreditation, Summary of Findings and Accreditation Certificate for all locations to the state governing body within 30 days of receipt.

E. Continued Compliance

Accreditation is contingent upon continued compliance with the standards and these accreditation policies and procedures.

Accreditation is not automatically renewable. Approximately 15 months prior to the organization’s expiration of accreditation, ACHC will notify the organization in writing and include a renewal application and PER. If renewal applications are not submitted when specified in the renewal letter, sufficient time may not exist to schedule and complete a survey prior to the organization’s expiration date. In this event, ACHC will automatically withdraw accreditation at the expiration of the current accreditation period. CMS and all appropriate regulatory agencies will be notified if an organization with deemed status loses its accreditation status. Renewal applications are processed through the accreditation process as stated in Section IV Accreditation/Survey Process.

After the organization is officially granted accreditation, ACHC reserves the right to make unannounced onsite visits at any time during a three-year accreditation cycle to determine continuing compliance with standards. If an interim visit reveals noncompliance with ACHC standards or Medicare COPs, a Plan of Correction and supportive documentation is required and full survey fees/expenses will be billed to the organization. ACHC conducts interim surveys based on a percentage of currently accredited organizations and/or patient complaints received by ACHC.

ACHC sends accredited organizations new/revised standards upon release, along with timeframes for organizations to come into compliance.

F. Appeals

Applicant organization may formally appeal the decision as provided in the Appeals Process.

Procedures for an Appeal of an ACHC decision are as follows:
1. An applicant organization or accredited organization must submit a written request to ACHC for an appeals hearing no later than 30 days from receipt of the letter informing them of the decision of their accreditation status.

2. ACHC will acknowledge, in writing, the receipt of the request and notify the Chairman of the Standards and Review Committee that an appeals hearing has been requested.

3. The Standards and Review Committee Chairman will consult with the Board Chairman to appoint a minimum of five members to an Appeals Hearing Committee. If the original decision was reached by members of the Standards and Review Committee, those members are not eligible to sit on the Appeals Committee.

4. The applicant organization or currently accredited organization has the option of submitting additional information or appear before the Appeals Hearing Committee. Any information submitted must have been in existence and available to the surveyor prior to the appeals hearing and during the latest site survey or interim site visit. Should the organization request an appearance before the Appeals Hearing Committee, a meeting will be scheduled and the organization will present explanations that will be considered by the committee.

5. The Appeals Hearing Committee will prepare a report of their findings for the Board.

6. The Board will review the findings of the Appeals Hearing Committee and make a final decision to uphold or reverse the original decision.

7. All appeal decisions made by the Board are final.

Any member of the Board or Standards and Review Committee who is affiliated with an organization under review or who has a conflict of interest must abstain from voting on the appeal under consideration.

VI. Notification of Changes

Post-Accreditation Changes

Accreditation is not automatically transferable when there is a merger or change in ownership. ACHC requires the organization to provide written notification thirty (30) days prior to a branch office addition or deletion, service addition or deletion, or change in the name, location, ownership or control of the organization.

Upon receipt of the appropriate documentation, including licensure and certification documentation from CMS/State Agency, ACHC will review for completeness and determine whether the organization’s accreditation certificate is still accurate. If an updated certificate(s) is required, a processing fee may be charged prior to issuance of a new certificate(s). Change in ownership or control of the organization may result in ACHC conducting onsite survey(s), with applicable survey fees.

Failure of the organization to notify ACHC of post-accreditation changes or provide additional requested information may result in assessment of penalties up to and including revocation of accreditation.

A. Name/Location Changes

The organization’s notification letter to ACHC must include the following:

1. Effective date of the change
2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter only for Name change or relocation to a different city.
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon written notification of a change in the organization's name, ACHC will review copies of the Articles of Incorporation and business license, if applicable. A new Certificate of Accreditation with the new name will be issued once ACHC receives the appropriate certificate re-issuance fee.

If the organization is relocated to a new city, ACHC will issue a new Certificate of Accreditation with the new location upon receipt of appropriate certificate re-issuance fees.

B. Merger/Ownership Changes

The organization's notification letter to ACHC must include the following:

1. Effective date of the change
2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter, if new certificate is required
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon execution of the state required filings of ownership change/merger, a letter documenting the transaction shall be submitted to ACHC, postmarked within 2 weeks of the effective date of filing.

Based on a review of documentation submitted, ACHC will make a determination whether an onsite survey, preparation of new Certificate of Accreditation, assessment of fees, and/or other action is required.

C. Branch Office Addition

ACHC defines a branch as a location serving clients/patients, maintaining client/patient and/or personnel records and accepting referrals and inquiries directly from potential clients/patients. A branch office that opens after accreditation is granted will not advertise or otherwise consider itself an accredited entity until official notification from ACHC.

If an organization adds a branch after its corporate accreditation takes place, ACHC requires the organization to provide written notification at least thirty (30) days prior to the opening/acquisition/merger which resulted in the new location. Failure to notify ACHC of this branch addition in the 30 day timeframe could result in disciplinary action. This letter should include the service(s) to be offered at each branch. Agencies that have deemed status will be surveyed after the CMS regional office approves the branch addition and authorizes ACHC to perform the survey, if applicable. Questions regarding this process should be directed to ACHC's Accreditation Department.
Upon receipt of the organization’s written notification, ACHC will send the organization a Branch Addition Application, Branch Addition Requirements List specific to the organization’s services provided, and notification of the fees required. The Branch Addition Requirements List outlines documentation necessary for ACHC to determine/conduct an offsite review or schedule an onsite survey of the new location.

ACHC reserves the right to conduct an onsite survey of any branch addition. If it is determined an onsite review is necessary, the normal unannounced survey scheduling process will apply and additional fees may be assessed.

A review of the documentation is performed and any missing information is requested from the organization in writing via fax/email/mail, along with timeframes for receipt. ACHC will hold the branch addition documentation without further processing until the missing information is received from the organization.

Upon approval, ACHC will mail a letter confirming accreditation of the new location for the duration of the corporate accreditation, and include an accreditation certificate.

D. Service Addition

ACHC requires the organization to provide written notification at least thirty (30) days prior to the addition of any service. Once ACHC is notified of the service addition, the company will receive the service addition application packet. Upon receipt of the completed application, the accreditation staff follows the application review, scheduling and contract preparation process.

ACHC will require a focused review and an onsite survey to determine if the organization is in compliance with applicable standards for the added service. If the data collected during the onsite survey reflects a passing score for the service(s), a certificate of accreditation for the service is issued for the duration of the current accreditation period.

E. Service Discontinuation

An accredited organization must notify ACHC in writing of any service that has been discontinued. A new service addendum may need to be completed for CMS purposes.

VII. Public Information

A. Logo/Advertising Language

An organization must accurately describe only the program(s), service(s) and branch office(s) currently accredited by ACHC and abide by the Guidelines for Use of ACHC’s Logo when advertising its accreditation status to the general public. False or misleading advertising represents noncompliance with accreditation and will result in penalties up to and including withdrawal of accreditation. The Guidelines for Use of ACHC’s Logo are sent to organizations in their accreditation notification packet. Branches and services accredited during the accreditation cycle can not be advertised as accredited until appropriate applications are submitted and accreditation certificates are received.

B. Press Releases

ACHC encourages organizations to publicize their accreditation status and provides a sample press release in the accreditation notification packet.
VIII. Nonconformance Policy

ACHC will process complaints, conduct investigations, discuss issues noted during surveys, and issue disciplinary actions according to the policies and procedures approved by the ACHC Board of Commissioners.

All disciplinary actions taken by ACHC will be reported on the ACHC Website. The information to be provided in these reports will include but is not limited to:
- organization name and address
- type of accreditation
- final action

A. Handling of Complaints

Complaints about accredited organizations are to be filed with the ACHC office. These complaints should identify facts or circumstances that relate to the complaint. ACHC will receive complaints by phone, mail, fax, email, the ACHC website or in person.

ACHC will investigate and/or review, and follow up on complaints from any source where an ACHC accredited organization appears to be out of compliance with its accreditation standards or Medicare COPs. As required by ACHC standards, accredited organizations must provide ACHC’s telephone number to their clients/patients as part of their client/patient hand-out for purposes of reporting a complaint.

Complaints should document:
- The name, mailing address and phone number of the person filing the complaint;
- The name of the organization involved;
- A detailed description of the incident that is the subject of the complaint, including identification of date, time, and location of each incident, as well as the identity of other individuals with information about the incident.

Anonymous complaints will not be accepted. The complainants’ identity will be kept confidential whenever possible. While under investigation by ACHC, a complaint is a confidential matter. However, ACHC cannot guarantee complainants that their identity will remain confidential if disclosed to ACHC. All substantiated findings become part of the permanent file of the organization involved and are public record.

Processing a Complaint

The ACHC Quality Assurance Manager or designee will inform the Senior Vice President of Clinical Compliance and Accreditation of the receipt of a complaint. Upon receipt of a complaint, a complaint file will be opened and the Quality Assurance Manager and the Senior Vice President of Clinical Compliance and Accreditation will conduct an initial review of the complaint to determine whether there is sufficient information presented to go forward with an investigation. This initial review consists of determining if the information presented meets the elements necessary to
proceed with further inquiry. To determine if an investigation of a complaint is warranted, the information gathered will be analyzed to determine whether, if true, it would constitute a violation of ACHC standards or Medicare Conditions of Participation. If upon initial review there is no evidence that a violation has occurred, the complaint is closed and the complainant will be notified that no breach of standard has occurred.

If the Quality Assurance Manager and Senior Vice President of Clinical Compliance and Accreditation conclude that the information shows that a violation may have occurred, the Quality Assurance Manager shall notify the organization that an investigation has been initiated. The investigation will be performed by the Quality Assurance Manager, as directed by and with the help of the Senior Vice President of Clinical Compliance and Accreditation. The organization or other subjects of the investigation may be interviewed and the organization may be asked for records for review during the investigation. An onsite survey may be required in order to complete the investigation.

If no violation is found following investigation, the Quality Assurance Manager will confer with the Senior Vice President of Clinical Compliance and Accreditation, at which time the complaint file may be closed. If closed, the complainant and the organization will be notified and no further action will be taken.

If sufficient evidence exists that the organization has violated the ACHC standards or Medicare Conditions of Participation, the organization may be penalized. If the organization is penalized at any level above a warning, the penalty will be listed on the ACHC website and CMS and/or other appropriate regulatory agencies will be notified.

If upon review of information it is determined that immediate jeopardy to the client/patient is present and ongoing, ACHC will notify the CMS regional office (RO) and conduct its investigation within two (2) business days of authorization from the RO. If it is determined the situation is non-immediate jeopardy, the complaint will be prioritized within two (2) business days of receipt and ACHC will conduct an investigation of the matter within 30 days to determine the exact nature of the complaint and the action warranted. Depending upon the nature of the complaint, one or both of the following actions may be taken:

1. ACHC will contact the organization, notifying it of the complaint and address the following:

   - provide a description of the complaint(s)
   - request the organization's cooperation in resolving the complaint
   - request the organization respond to the complaint within the identified time frame
   - ask the organization if they were aware of the complaint and if they have taken action

2. ACHC may contact the organization via phone and/or fax or designate personnel to go unannounced to the organization and request immediate access to information and data related to the standards indicated in the complaint.

ACHC will review all the information and data collected relative to the complaint. If necessary, a summary report will be sent to the Standards and Review Committee for a final decision. If an investigation reveals the complaints allegations are substantiated and the patient's health, safety and welfare are in jeopardy, the organization may face disciplinary action, including suspension or revocation of accreditation.

If any noncompliance with ACHC standards or Medicare COPs is confirmed during the onsite
complaint investigation survey, a plan of correction and supportive documentation is required and survey fees/expenses will be billed to the organization. If ACHC makes the decision to withdraw accreditation, ACHC will notify the appropriate regulatory bodies of its decision.

B. Disciplinary Actions as a Result of Survey Findings

Disciplinary actions can also results from information gathered during a survey. Failure to adhere to certain standards and/or Medicare COPs, failure to follow ACHC policies and procedures or failure to submit and follow an appropriate plan of correction will result in a disciplinary action. Investigations regarding issues found during the survey process may be further investigated by a request for documentation, interviews and/or unannounced on-site surveys. The organization will be billed for surveys conducted as a result of a disciplinary action.

C. Overview of Disciplinary Actions

The following are Disciplinary Actions authorized by the Accreditation Commission for Health Care to discipline an organization for violations of ACHC standards and Medicare Conditions of Participation:

1. Warning
2. Reprimand
3. Probation
4. Suspension
5. Revocation

Warning

A warning is a written communication between ACHC and the organization that serves as notice that an ACHC standard or Medicare Condition of Participation may have been breached, but the conduct does not rise to the level which warrants public censure. A warning may be issued by the Senior Vice President of Clinical Compliance and Accreditation to an organization. It is a minimal disciplinary action and is not considered public information.

A warning will be issued following an investigation if the Senior Vice President of Clinical Compliance and Accreditation acting on behalf of ACHC, believes that there is insufficient evidence to support a disciplinary action against the organization, but there is sufficient evidence to notify the organization that continuing the activities which led to the complaint being submitted to ACHC may result in action against the organization.

Reprimand

A reprimand is a formal sanction that expresses concern about the actions of an organization but does not restrict accreditation certification. A reprimand is considered public information and will be reported to national and state regulatory agencies. A reprimand may be issued by the Senior Vice President of Clinical Compliance and Accreditation to an organization if there is sufficient evidence that a violation of a statute(s), accreditation standards, and/or rules has occurred, but the violation is not of sufficient seriousness to warrant suspension or revocation of the accreditation.
Probation

ACHC may determine that it is appropriate to allow an organization continued accreditation and not revoke or suspend the organization's accreditation. In assessing the appropriateness of a probationary penalty, ACHC will consider all the facts and circumstances of the conduct at issue and the organization's prior performance. In particular, ACHC will review the nature, severity, and scope of the violation, the degree and scope of harm to patients and the nature of the motivations of the organization that led to the conduct in question.

Further, in assessing the overall appropriateness of probation and in defining the appropriate duration of the probation, ACHC also will review the organization’s service performance, prior history of violations of ACHC’s standards or accreditation policies and procedures, especially prior violations of the provisions that relate directly to the conduct then in question, and also whether any probationary condition that might be imposed will provide sufficient safeguards to ensure the safety and welfare of the public as well as the successful remediation of the organization’s conduct. A probationary sanction may be invoked for a period not to exceed three (3) years since situations that would require monitoring for a period longer than that are inappropriate for a probationary sanction. Probation may be offered to an organization by ACHC as part of the issuance of a new accreditation certification. Failure to comply with the stated conditions is grounds for suspension or revocation of the accreditation.

The Senior Vice President of Clinical Compliance and Accreditation may place an organization on probation after presenting the facts of the investigation to the Standards and Review Committee. Decisions regarding probation will be made by the Standards and Review Committee. Probation is considered public information and will be reported to the appropriate state and national regulatory agencies and listed on the ACHC website.

Suspension

When ACHC determines it is appropriate, it places an organization on suspension of accreditation for a fixed period of time up to six (6) months, with the understanding that at the end of the specified period of time, and with the completion of any additional conditions including, but not limited to, completion of corrective actions or monitoring of particular areas of practice or conduct that successfully demonstrate successful outcomes relative to investigational findings, the accreditation will automatically be reinstated and reissued upon the organization’s payment of the standard cost for the issuance of a replacement accreditation certificate. The Senior Vice President of Clinical Compliance and Accreditation may place an organization on probation after presenting the facts of the investigation to the Standards and Review Committee. Decisions regarding suspension will be made by the Standards and Review Committee. Suspensions are considered public record and will be reported to all appropriate agencies and listed on the ACHC website.

Revocation

Revocation entails loss of accreditation for a specified period of time. Accreditation may be reissued after the specified period has expired and the organization has petitioned for reinstatement, and provided sufficient evidence of compliance with accreditation standards, Medicare Conditions of Participation and any conditions imposed by ACHC at the time of the revocation. Decisions regarding revocation will be made by the Standards and Review Committee. Revocation decisions are considered public record and will be reported to all appropriate agencies and listed on the ACHC website.
Obtaining Records for Investigation

ACHC may request the organization to produce records to allow ACHC to investigate the organization. ACHC’s Senior Vice President of Clinical Compliance and Accreditation is authorized by ACHC to request all needed records for investigation purposes. Each request will identify the pertinent document or records needed by ACHC. A time shall be specified in the request by which the documents shall be produced.

In issuing requests for documents, ACHC shall make every effort to limit its request to the minimum necessary information required in order to complete its investigation and will also otherwise comply with the Privacy Rule adopted by the United States Department of Health and Human Services and codified at 45 CFR § 164.500 et seq.

Reporting of Disciplinary Actions

All disciplinary actions taken by ACHC will be reported in the Surveyor Newsletter and on ACHC’s website. In addition, as required by federal law, a report of actions will be made to all applicable local, state and federal regulatory agencies. ACHC will report any probation, revocation or suspension of an organization’s accreditation to all appropriate regulatory bodies including Centers for Medicare and Medicaid, National Supplier Clearinghouse and state licensure agencies. The information to be provided includes:

- Facility name and address
- Owner name(s) and address(s) and/or Board of Director(s)
- Type of accreditation (Initial or Renewal)
- Disciplinary action
Date: September 28, 2010

To: Licensing Committee

Subject: Agenda Item 2: Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include “Self-Query” Reports from the National Practitioners Data Bank -- Healthcare Integrity and Protections Data Bank

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 in the next agenda item.

As you will remember, 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.

For pharmacists: Amend section 1728 to 16 CCR:

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 from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank, dated no earlier than 60 days of the date the application for examination as a pharmacist was/will be 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.

For Interns: Add section 1727.2 to 16 CCR:

1727.2 Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank, dated no earlier than 60 days of the date the application was/will be submitted to the board.
Date: September 28, 2010

To: Licensing Committee

Subject: Agenda Item 3 --
Modifications to the Pharmacy Technician Application – 16-CCR 1793.5

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.

During this meeting, the committee will have an opportunity to review proposed modifications to the pharmacy technician application. Under policies of the Office of Administrative Law, applications generally must be adopted as regulations or alternatively applications can be referenced in regulations by date and form number. We have done the latter for the technician application, which is why we not need to go into a rulemaking to modify the application form.

Additionally, the 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.

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 application.

Following this page are proposed amendments to the application form and a proposed modification to section 1793.5 to require NPDB-HIPDB as part of the application process for pharmacy technicians.
To Amend 1793.5. 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 30-60 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.
APPLICATION FOR REGISTRATION AS A PHARMACY TECHNICIAN

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

<table>
<thead>
<tr>
<th>Full Legal Name-Last Name:</th>
<th>First Name:</th>
<th>Middle Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Names (AKA, Maiden Name, Alias, etc):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Official Mailing/Public Address of Record (Street Address, PO Box #: etc):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Residence Address (if different from above):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>**Social Security No:</td>
<td>Driver's License No:</td>
<td></td>
</tr>
<tr>
<td>Date of Birth (Month/Day/Year):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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 17920 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 Education (check one box)

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

- [ ] High school graduate Date graduated: ____________________________
- [ ] Completed General Education Development (GED) Date GED awarded: ____________________________

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(1234) 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 a certified copy of PTCB certificate - Date certified: ____________________________
- [ ] Attached a certified copy of your military training DD214

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

FOR BOARD USE ONLY

<table>
<thead>
<tr>
<th>Photo</th>
<th>En' 1st Check</th>
<th>En' 2nd Check</th>
<th>Qualify Code</th>
<th>FP Cards/Live Scan</th>
<th>FP Cards Sent</th>
<th>FP Fees</th>
<th>DOJ Clear Date</th>
<th>FBI Clear Date</th>
<th>Registration no</th>
<th>App fee no</th>
<th>Date issued</th>
<th>Amount</th>
<th>Date expires</th>
<th>Date cashiered</th>
</tr>
</thead>
</table>

DRAFT LANGUAGE FOR BOARD CONSIDERATION – NOT YET NOTICED FOR PUBLIC COMMENT 16 CCR § 1793.5
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.

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.  
   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 registration should be issued, whether conditions should be imposed, or whether you are not eligible for registration.  

2. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?  
   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?  
   Attach a statement of explanation.

3. Has disciplinary action ever been taken against your pharmacist license, intern permit or technician registration 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.

4. Have you ever had an application for a pharmacist license, intern permit or technician registration 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.

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.

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.

7. Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?  
   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, misdemeanors, 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.  
   Check the box next to "NO" if you have not been convicted of a crime.  
   You may wish to provide the following information in order to assist in the process 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.  
   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.

<table>
<thead>
<tr>
<th>Arrest Date</th>
<th>Conviction Date</th>
<th>Violation(s)</th>
<th>Court of Jurisdiction (Full Name and Address)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

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 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
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

☐ 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: ____________________

17A-5 (Rev. 08/10) 4
PHARMACY TECHNICIAN REGISTRATION APPLICATION INSTRUCTIONS

YOU MUST SATISFY ALL REQUIREMENTS FOR LICENSURE AT THE TIME OF SUBMITTING THE APPLICATION.

APPLICATION PROCESSING TIMEFRAME
- Please allow the board 30 days to process your application. The board will mail you a deficiency letter if your application is incomplete.
- Due to current workload the board will not be able to respond to status checks on your application unless your application has been on file for over 60 days.
- You may wish to confirm with your bank if your check as been processed as verification the board received your application.
- To verify if your license has been issued, please visit the board’s website at www.pharmacy.ca.gov under “Verify a License”, as the processing time to receive your license wallet certificate is 4-6 weeks from the date the license is issued.

APPLICATION INSTRUCTIONS
Print out the entire application and required forms as instructed under the section entitled What Makes an Application Complete on page 2 of these instructions. Please review the Qualifying Method section below to ensure you qualify and What Makes an Application Complete section below to ensure you have completed and included all the required forms prior to submitting your application to the board.

PLEASE NOTE: It is very important that when you complete the application, your name you apply under IDENTICALLY matches the name on your United States (U.S.) government issued photo identification (state issued driver’s license or state issued identification card) AND the name on your Request for Live Scan form or fingerprint cards.

QUALIFYING METHOD
To be licensed as a pharmacy technician in California, you must qualify under A, B, or C as listed below:

A. If you are qualifying by one of the following methods, the Affidavit of Completed Coursework or Graduation for Pharmacy Technician (page 4 of the application) must be submitted with your application.
   - An Associate degree in pharmacy technology;
   - Any other course that provides a minimum of 240 hours instruction as specified in Title 16 California Code of Regulations Section 1793.6(c);
   - A training course accredited by the American Society of Health-System Pharmacists (ASHP); or
   - Graduation from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE).

B. If you are certified by the Pharmacy Technician Certification Board (PTCB), you must submit a certified true copy of your PTCB certificate with your application. (A certified true copy is a copy that has been certified or notarized as a true copy.)

C. If you are qualifying by training provided by a branch of the federal armed services, you must submit the original or a certified true copy of your DD214 with your application. (A certified true copy is a copy that has been certified or notarized as a true copy.)
WHAT MAKES AN APPLICATION COMPLETE (Please use the following checklist to assist you in ensuring your application is complete prior to submitting your application to the board.) If your application is incomplete, the board will notify you of any deficiencies. Failure to complete your application within 60 days after being notified by the board of any deficiencies will result in your application being deemed abandoned and you will be required to file a new application and meet all of the requirements in effect at the time of reapplication.

☐ APPLICATION FEE $80: Submit a check, money order, or cashier's check in the amount of $80, made payable to the Board of Pharmacy with your application. The application fee is non-refundable.

☐ APPLICATION FOR REGISTRATION AS A PHARMACY TECHNICIAN (form 17A-5 (rev. 7.10)): The application must be completed in its entirety. Failure to do so will result in an incomplete application and a deficiency letter being mailed to you. A passport style photo (2" x 2") must be taken within 60 days of filing the application, and must be attached to the front of the application. (Scanned images and Polaroid pictures are not accepted as the images decay over time.) You need to complete, sign, and date the application. Do not allow your school to complete page 1, 2, and 3 of the application.

☐ FINGERPRINTS: All applicants are required to have their fingerprints processed via Live Scan if they reside in California. If you reside outside of California and are unable to visit California to do the Live Scan, then you must have your fingerprints processed on the Board of Pharmacy issued fingerprint cards. DO NOT complete the Live Scan or fingerprint cards until you are ready to submit your application. The board will only accept current fingerprint clearances from Department of Justice (DOJ) and Federal Bureau of Investigation (FBI). Detailed instructions for fingerprints are provided below. Submit either A or B below with your application:

A. Completed Live Scan receipt, showing submission information.

    OR

B. Completed fingerprint cards along with the additional $51 for the fingerprint card processing fee. Submit the fingerprint card processing fee with the application fee when submitting your application to the board.

☐ QUALIFYING DOCUMENTATION: You are required to include with your application the Affidavit of Completed Coursework or Graduation for Pharmacy Technician, a certified copy of your PTCB certification, or a certified copy of your military training. The Qualifying Method on page 1 of these instructions identifies which document you need to provide.

FINGERPRINT SUBMISSION INSTRUCTIONS
The board requires the applicant to have their fingerprints submitted at the time a pharmacy technician application is submitted to the board regardless of any prior fingerprint submission for other applications with the board.

A. CALIFORNIA RESIDENT: Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the instructions for completing a "Request for Live Scan Service" form in this application package. The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach a completed copy of the Live Scan form to your application and submit to the board (this is your Live Scan receipt).

Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice Web site at: http://ag.ca.gov/fingerprints/publications/contact.pdf
STEPS TO ENSURE YOUR LIVE SCAN FORM IS COMPLETED ACCURATELY BY THE LIVE SCAN OPERATOR

It is the applicant’s responsibility to ensure that the information the Live Scan operator types into the computer system is correct before the Live Scan operator submits the transmission. Please verify the following information is correct:

- The Live Scan operator selects BOTH the DOJ and FBI prior to submitting the request. If FBI is not selected at the time of original transmission, you may be required to have your Live Scan redone at another time and have to repay for the DOJ and FBI levels of services again. The board has been notified by the DOJ that effective 9/1/07; if the FBI level of service is not requested at the time of original transmission both DOJ and FBI levels of service will have to be redone. Any issue of cost for resubmission should be handled at the Live Scan Site level.

- Verify on the Live Scan operator’s computer that the below information has been typed correctly:
  - Full Name is spelled correctly and matches your I.D (Jr., II, etc must be included in the name). Your name must match your full name on your application.
  - Date of Birth is correct.
  - US Social Security Number is entered and correct. This is required and must be entered.
  - License type needs to be entered as: Pharmacy Tech-Sect 4015.

The board has seen an increase in the number of Live Scan transmissions where the name, date of birth, or the US social security number has been entered incorrectly or does not IDENTICALLY match the applicant’s identification and the full legal name on the application. If such information is entered incorrectly, the applicant will be required to redo the Live Scan process again. This is usually at the expense of the applicant. This will result in a delay in processing your application.

B. NON-CALIFORNIA RESIDENTS: If you reside outside California, you must submit rolled fingerprints with your application on Board of Pharmacy fingerprint cards along with fee fingerprint card processing fee of $51 made payable to the Board of Pharmacy ($32 DOJ fee and $19 FBI fee). You may contact the board to request the fingerprint cards at (916) 574-7900 or email your request to rxforms@dca.ca.gov.

Fingerprints submitted on the fingerprint cards must be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take longer than the Live Scan process, by approximately six weeks. Poor quality prints may result in rejection of the card and will substantially delay licensing since additional fingerprint cards will be required from you for processing.
APPLICATION FOR REGISTRATION
AS A PHARMACY TECHNICIAN

(Please print or Type)

Name: Last       First       Middle       Former

Address: Number       Street

City       State       Zip

Telephone Number       Driver License Number/State

Work:       Home:

Date of Birth       Social Security Number*

A & B: EDUCATION/TRAINING

Name of University, College, School or Organization: Date of Completion/Graduation

Address of University/College, School or Organization: Number       Street       City       State       Zip Code

C: PHARMACIST EXAM

Are you eligible to take the Pharmacist licensure exam? Yes □ No □

D & E: EXPERIENCE - List all qualifying experience earned in and out-of-state.

<table>
<thead>
<tr>
<th>Dates</th>
<th>Name and Address of Employers</th>
<th>Total Hours Experience</th>
<th>Name of Pharmacist Having Direct Knowledge of Your Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>From</td>
<td>To</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Complete Reverse Side

DO NOT WRITE BELOW THIS LINE

FP Cards □ Photo □ Exp Aff □ Hours Verified □

To DOJ □ FP Clearance □
Qualify Code □ Transcript □
Training Cert □ TC Code □

App Fee No. □
Amount $ □
Date Cashiered □
License No. □
Date Issued □
II it s of information requested in this application are mandatory. Failure to provide any of the information in the application being rejected as incomplete. The information will be used to determine compliance with the California Pharmacy Law. The official responsible for information maintenance is the Law Enforcement Officer, telephone (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814. The information may be transferred to another governmental agency such as law enforcement agency if necessary for it to perform its duties.

If an answer to questions 1 through 5 is Yes, you must attach a written explanation giving full details for each affirmative response. Failure to provide an explanation will delay the process of your application.

I 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 the foregoing application, including all supplementary statements.

Disclosed your social security number is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (2 USC 405(c)(2)(C) authorize collection of your social security number. Your social security number will be used exclusively for tax enforcement purposes and for purposes of compliance with any judgment or order for family support in accordance with Section 11565.6 of the Welfare and Institutions Code. If you fail to disclose your social security number, you will be reported to the Franchise Tax Board, which may assess a $100.00 penalty against you.

QUESTION CONCERNING THIS REQUIREMENT MUST BE DIRECTED TO THE FRANCHISE TAX BOARD:

Southern California (800) 852-7000 - Northern California (800) 852-5700 - Out of State or Sacramento Area (916) 269-3500.

STATEMENT OF APPLICANT

I 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 the foregoing application, including all supplementary statements.
Date: September 28, 2010
To: Licensing Committee
Subject: Agenda Item 4:
Request from PETNET Solutions for a Waiver of Security Requirements for pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present

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 is requesting the following waivers:
1. Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a)
   o 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.

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
(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.

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 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 said application, should the board grant a waiver, or comply with other actions as determined by the board.

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.
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. The two sections are provided below.

4118. Waiving of Minimum Requirements by Board
(a) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements.
(b) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a hospital pharmacy, as defined by subdivision (a) of Section 4029, that does not meet all of the requirements for licensure as a hospital pharmacy, the board may waive any licensing requirements. However, when a waiver of any requirements is granted by the board, the pharmaceutical services to be rendered by this pharmacy shall be limited to patients registered for treatment in the hospital, whether or not they are actually staying in the hospital, or to emergency cases under treatment in the hospital.

1707.6 Experimental Programs In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:
(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.
(b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.
(c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

One of the board’s Supervising Inspectors has indicated concern with this request. Specifically that Business and Professions Code section 4116 provides essentially that no person shall be in the pharmacy unless the pharmacist is present, and 16 CCR 1714 requires that the key to the pharmacy is restricted to a pharmacist. PETNET is working with a solution to their operational needs without a waiver – retain a pharmacist during those non-operational times when the pharmacy needs to do maintenance/inventory/cleaning).
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
Date: September 28, 2010

To: Licensing Committee

Subject: Agenda Item 5 -- Discussion Surrounding Dedicated CE

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.

At this meeting, the committee will have an opportunity to discuss such a requirement. I believe that prior discussions have included the need to earn CE in emergency response, patient consultation or in maintaining control of a pharmacy’s drug inventory.

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.

Currently the board has 36,000 active pharmacist licensees, and 2,266 inactive pharmacists (who are not required to earn CE to renew).
Article 17. Continuing Education

4231. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
(a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.
(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.
(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.
(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

4232. Content of Courses
(a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy education.
(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.
(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

4234. Exceptions: Emergencies; Hardship
The board may, in accordance with the intent of this article, make exceptions from the requirements of this article in emergency or hardship cases.

Board Regulations:

Article 4. Continuing Education

1732. Definitions.
As used in this article:
(a) “Accreditation agency” means an organization which evaluates and accredits providers of continuing education for pharmacists.
(b) “Hour” means at least 50 minutes of contact time.
(c) “Provider” means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.


1732.05. Accreditation Agencies for Continuing Education.
(a) The following organizations are approved as accreditation agencies:
(1) The Accreditation Council for Pharmacy Education.
(2) The Pharmacy Foundation of California.
(b) Accreditation agencies shall:
(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider’s ability to comply with the requirements of section 1732.1 of this Division.
(2) Maintain a list of the name and address of person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
(3) Provide the board with the names, addresses and responsible party of each provider, upon request.
(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board; and
(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.
(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

1732.1. Requirements for Accredited Providers.
(a) No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.
(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.
(c) Providers shall furnish statements of credit to all participants that complete a continuing education course. The statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.
(d) Each provider shall notify the accreditation agency at least 15 days in advance of the first time each new continuing education course is offered or presented.
(e) Providers shall maintain records of completion of their continuing education courses for four years.
(f) Providers shall include the following information in promotional materials regarding continuing education courses:
   (1) Provider's name.
   (2) The number of hours awarded for completion of the course.
   (3) The date when the course’s accreditation expires.
   (4) The provider number assigned by the accreditation agency.
   (5) The name of the provider’s accrediting agency.
   (6) The learning objectives of the program.
   (7) The nature of the targeted audiences that may best benefit from participation in the program.
   (8) The speakers and their credentials.
   (g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

1732.2. Board Accredited Continuing Education.
(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.


1732.3. Requirements for Continuing Education Courses.

(a) Unless denied by the accreditation agency upon audit, all coursework offered by providers may be used to satisfy the continuing education required by section 1732.5 of this Division.

(b) On a random basis or in response to a request by the board, the accreditation agency shall review selected coursework. The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section.

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

(d) Continuing education courses shall comply with the following:

1. Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

2. Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

3. Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

4. Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:

   A. The scientific knowledge or technical skills required for the practice of pharmacy.

   B. Direct and/or indirect patient care.

   C. The management and operation of a pharmacy practice.

   (2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.


1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course, each provider shall submit such materials as are required by the accreditation agency.


1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.


1732.6. Exemptions.
Pharmacists may seek exemption from the continuing education requirements for renewal on the grounds of emergency or hardship by applying to the board in writing, setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.


1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board.

In March, the Federal Health Care Reform Act was enacted federally. Since the last Licensing Committee Meeting in June, 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.

A copy of this memorandum follows.

At this meeting, staff had sought to have a presentation of the impact of this federal legislation on California’s health care workforce. This presentation instead is being scheduled for the October Board Meeting.
DATE       June 23, 2010

TO          Executive Officers, Healing Arts Boards

FROM        Brian J. Stiger, Director

SUBJECT     Federal Healthcare Reform – Impact on DCA

Introduction
The federal government recently enacted the Patient Protection and Affordable Care Act (PPACA), which will dramatically change many aspects of healthcare coverage for many Americans. As the scope and impact of this complicated legislation becomes more clearly understood, we must proactively anticipate how healthcare delivery in California will change and plan for the inevitable impact upon the healing arts boards. The purpose of this memorandum is to reinforce the importance of healthcare reform as a critical planning item and to begin a discussion on its potential impact to our boards. With this in mind, I am providing a broad outline of the scope of the PPACA and a brief discussion of how we may be impacted.

PPACA
The federal healthcare reform act is an extremely broad and sweeping reform of how health insurance will be provided and delivered in the United States. Some of the key provisions of the PPACA, and those that will likely be the most visible and impactful to the general public are as follows:

- **Individual Insurance Mandate**: Beginning in 2014, most U.S. citizens and legal residents will be required to carry a minimum level of health insurance or face a monetary penalty.
- **Health Insurance Exchanges**: States will be required to establish a health insurance exchange by 2014. The purpose of the exchange is to provide a simplified system through which individuals and small businesses may shop for and purchase health insurance from participating providers. There is flexibility for states in how they wish to establish and manage the exchanges and there is the option for states to rely on a federally managed exchange.
- **Subsidies to Low-Income Persons for Coverage**: The PPACA provides for subsidies that persons meeting certain low-income criteria may receive to apply toward the cost of health insurance.
- **Employer Requirements**: Employers will not be directly required to provide health coverage to employees, but will be strongly incentivized to do so in the form of penalties for failing to provide affordable (as defined) coverage.
Private Health Insurance Practices: Beginning this year and phasing in over the next few years, there will be a variety of new restrictions and requirements placed upon private health insurance companies. These include, for example, no refusals based on preexisting conditions, no lifetime limits of coverage, mandatory full coverage of preventative care services (immunizations, routine exams, etc.), and an extension of dependent coverage for dependents under age 26.

Expansion of Medicaid: PPACA significantly expands the Medicaid program (Medi-Cal in California) by mandating coverage of certain populations not currently covered. By 2014, the law will require essentially all individuals under age 65 at or below 133% of the federal poverty level to be covered under Medicaid.

Basic Health Plan: States have the option of implementing a “Basic Health Plan” that would provide options for certain low-income level persons that do not qualify for Medicaid but do not have access to employer coverage or resources to afford plans available through the Health Insurance Exchanges.

Opportunities to Improve Health Care: The PPACA contains a variety of grants, incentives and programs designed to improve access, quality, delivery and outcomes in health care.

Impact on the Department of Consumer Affairs

The primary and most direct impact on California government resulting from the PPACA will be on the health insurance-related agencies such as the Department of Health Care Services, the Department of Insurance and the Department of Managed Health Care. These agencies will bear the brunt of reorganizing and implementing the changes in coverage mandated by the federal law.

A big increase in coverage, however, will translate to a big increase in the number of patients. Additionally, with incentives created for all patients to obtain more routine and preventative care, there will very likely be a surge in the number of patients seeking these types of services. This surge will, in turn, create a demand for more healthcare personnel, particularly in areas of primary care. This ripple effect will eventually hit our healing arts boards, which will feel the pressure to license a greater number of licensees. The increase in the workload of and demand for more medical-related licensees could adversely impact the boards’ licensing and enforcement activities. The healing arts boards should prepare for increased licensing activity over the next several years. Further, a surge in need for personnel could lead to a rapid increase in private for-profit and nonprofit training programs, creating an increase in the workload of not only the healing arts boards, but also the Bureau for Private Postsecondary Education.

All healing arts boards should immediately begin to consider the following key areas with respect to accommodating the impending surge in the number of patients with health insurance:

- Handling a larger licensing/registration volume for healthcare personnel.
- Accreditation/approval of new private and public training programs.
- How to respond to proposals that would affect scope of practice, particularly in areas of preventive and primary care.
- Testing, educational and interstate-reciprocity prerequisites for licensure.

As a part of this consideration, boards should evaluate current regulations and practices to identify areas in which the status quo may unnecessarily hinder the efficient expansion of the licensed healthcare workforce.
Encouraging and Facilitating a Better Healthcare Workforce

The PPACA includes a variety of measures designed to create opportunities for improvements in health care generally. A detailed list of all of these grants and programs is beyond the scope of this memorandum, but the following are a few representative examples:

- Increases in the amounts available for nursing program student loans.
- Grant program to support new or expanded residency programs in primary care at teaching health facilities.
- Pediatric Specialty Loan Repayment Program through which pediatric specialists providing specified services in underserved areas may receive funds for loan repayment.
- Grants for the operation of school-based health centers.

The Department and boards may benefit from investigating those newly created programs and grants affecting the individual practice areas and proactively informing current and prospective licensees about those that might benefit them. We should ensure that, whenever possible, California licensees, both current and prospective, can qualify for federal programs. Further, boards may also benefit from identifying other state and local programs that encourage the expansion of the primary care workforce.

Boards should also continue to examine and reexamine current practices in an effort to identify areas that could unreasonably or unnecessarily restrict the expansion of California’s healthcare workforce. For instance, boards may wish to look at license reciprocity issues. On the administrative end, boards should consider issues such as inefficient or backlogged licensing processes, frequency of licensing exam administration and adequacy of staff resources, all with an eye toward accommodating the need for a larger workforce.

Conclusion

The eventual impact of healthcare reform is uncertain. The changes to the health insurance industry made by the PPACA are unprecedented and there is no way to truly predict exactly how California’s healthcare system will be affected. There is no doubt, however, that we need to be proactive in its handling of reform. California’s newest patients should not find themselves in a system ill-equipped to provide them with the healthcare staff they need to make their health coverage meaningful.

In the weeks and months ahead, I look forward to working with all of you to assess the potential impact that healthcare reform will have on your programs and share innovative and creative ideas for helping all of us address and manage the change.
Date: September 28, 2010
To: Licensing Committee
Subject: Competency Committee Update

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. As of the date of this report, the quality assurance review has been removed and results have been released.

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.
Date: September 28, 2010

To: Licensing Committee

Subject: Agenda Item 8: Quarterly Licensing Statistics

On the following pages are licensing statistics for the board.
## Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

### APPLICATIONS

<table>
<thead>
<tr>
<th>Received</th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist (exam applications)</td>
<td>137</td>
<td>102</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>239</td>
<td></td>
</tr>
<tr>
<td>Pharmacist (initial licensing applications)</td>
<td>203</td>
<td>343</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>546</td>
<td></td>
</tr>
<tr>
<td>Intern pharmacist</td>
<td>50</td>
<td>472</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>522</td>
<td></td>
</tr>
<tr>
<td>Pharmacy technician</td>
<td>776</td>
<td>955</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1731</td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td>19</td>
<td>28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Pharmacy - Temp</td>
<td>0</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>5</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Sterile Compounding - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Clinics</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>6</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Hospitals - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Nonresident Pharmacy</td>
<td>4</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Nonresident Pharmacy - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Licensed Correctional Facility</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hypodermic Needle and Syringes</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Nonresident Wholesalers</td>
<td>10</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Nonresident Wholesalers - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Wholesalers</td>
<td>7</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Wholesalers - Temp</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Designated Representatives</td>
<td>36</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>78</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1259</td>
<td>1984</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3243</td>
<td></td>
</tr>
</tbody>
</table>

* u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010
<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Issued</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>179</td>
<td>471</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>650</td>
</tr>
<tr>
<td>Intern pharmacist</td>
<td>72</td>
<td>310</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>382</td>
</tr>
<tr>
<td>Pharmacy technician</td>
<td>752</td>
<td>932</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1684</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>21</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>39</td>
</tr>
<tr>
<td>Pharmacy - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Sterile Compounding - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Clinics</td>
<td>9</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Hospitals</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Hospitals - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Nonresident Pharmacy</td>
<td>4</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Nonresident Pharmacy - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Licensed Correctional Facility</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Hypodermic Needle and Syringes</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Nonresident Wholesalers</td>
<td>4</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Nonresident Wholesalers - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesalers</td>
<td>4</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Wholesalers - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer - Temp</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Designated Representatives</td>
<td>16</td>
<td>29</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1067</td>
<td>1778</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2845</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pending</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist Examination</td>
<td>725</td>
<td>566</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1291</td>
</tr>
<tr>
<td>Intern pharmacist</td>
<td>270</td>
<td>441</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>711</td>
</tr>
<tr>
<td>Pharmacy technician</td>
<td>2505</td>
<td>2550</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5055</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>75</td>
<td>81</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>156</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>24</td>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>Clinics</td>
<td>29</td>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>55</td>
</tr>
<tr>
<td>Hospitals</td>
<td>8</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Nonresident Pharmacy</td>
<td>43</td>
<td>51</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>94</td>
</tr>
<tr>
<td>Licensed Correctional Facility</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Hypodermic Needle and Syringes</td>
<td>12</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>27</td>
</tr>
<tr>
<td>Nonresident Wholesalers</td>
<td>78</td>
<td>86</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>164</td>
</tr>
<tr>
<td>Wholesalers</td>
<td>48</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Designated Representatives</td>
<td>188</td>
<td>197</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>385</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4005</td>
<td>4096</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8101</td>
</tr>
</tbody>
</table>

* u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010
### Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

#### Change of Pharmacist-in-Charge***

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>104</td>
<td>128</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>232</td>
<td></td>
</tr>
<tr>
<td>Processed</td>
<td>118</td>
<td>132</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>250</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td>389</td>
<td>385</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>774</td>
<td></td>
</tr>
</tbody>
</table>

#### Change of Exemptee-in-Charge***

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>8</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Processed</td>
<td>4</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td>108</td>
<td>117</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>225</td>
<td></td>
</tr>
</tbody>
</table>

#### Change of Permits

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>48</td>
<td>69</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>117</td>
<td></td>
</tr>
<tr>
<td>Processed</td>
<td>4</td>
<td>44</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td>222</td>
<td>247</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>469</td>
<td></td>
</tr>
</tbody>
</table>

#### Discontinuance of Business***

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>20</td>
<td>21</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>Processed</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td>135</td>
<td>156</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>291</td>
<td></td>
</tr>
</tbody>
</table>

#### Renewals Received

<table>
<thead>
<tr>
<th></th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>APR</th>
<th>MAY*</th>
<th>JUN*</th>
<th>FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy technician</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinics</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonresident Pharmacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Licensed Correction Facility</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypodermic Needle and Syringes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonresident Wholesalers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wholesalers</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veterinary Food-Animal Drug Retailer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Designated Representative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010