



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Licensing Committee Report

Members:

Greg Lippe, Public Member, Chairperson

Ryan Brooks, Public Member

Kenneth Schell, PharmD

Debbie Veale, PharmD

LICENSING COMMITTEE REPORT AND ACTION

Report of the Meeting held on DECEMBER 2, 2010.

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

Attachment 1

Relevant Statutes

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

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

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

Background

In 2003, two accreditation agencies received board approval: 1. Accreditation Commission for Health Care, Inc. (ACHC), and 2. Community Health Accreditation Program (CHAP). Since that time board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. Currently the board has 225 such licensed facilities in California and 78 nonresident pharmacies with such permits.

Also in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should

be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

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

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. Also, modified regulations detailing requirements for pharmacies that compound medication took effect July 7, 2010. Included in these regulations are modified requirements for pharmacies that compound sterile injectable medication.

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

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

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

Committee Discussion/Action

The committee was advised of the assessment results completed by Supervising Inspector Janice Dang for both Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP). She provided a comparison of both agencies and reviewed site inspection results from 2 pharmacies for each agency.

Based on the information provided, the committee sought clarification on areas of possible concern and requests were made to CHAP and ACHC to provide information to the board by January 10, 2011 regarding how many sterile injectable compounding pharmacies have

been accredited, reaccredited, placed on provisional status, withdrawn, and denied within the last five years as well as validation information.

Attachment 1 contains several items:

- Detailed Comments of ACHC
- Supplemental Information received from ACHC
- Detailed Comments of CHAP
- Supplemental Information received from CHAP
- Comparison of all 4 accreditation agencies
- Results of Site inspections of pharmacies accredited by each agency

Terry Duncombe, representing CHAP and Tim Safley, representing ACHC will both be present at the board meeting.

MOTION: LICENSING COMMITTEE: Recommend to the board that ACHC and CHAP be reapproved as accreditation agencies for three years pending receipt of the requested information.

b. FOR DISCUSSION: Update on the Board's Psychometric Evaluation for the ExCPT and PTCB Examinations

Relevant Statutes

Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. There are several routes to licensure:

- Obtain an associates degree in pharmacy technology
- Completion of a technician training course
- Graduation from a school of pharmacy recognized by the board
- Certification by the Pharmacy Technician Certification board

Business and Professions Code Section 139 requires a psychometric assessment description of the occupational analysis serving as the basis for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Background

During the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT).

The results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam, consistent with the requirements in B&PC 139.

Since that time, board staff has pursued several options to facilitate these evaluations; however because of contract restrictions including freezes, work could be initiated. Last

year the board was advised that the department's Office of Professional Examination Services would be available to conduct these evaluations for the board.

Committee Discussion/Action

The committee was advised that work is scheduled to begin in January 2011 and should be completed in June 2011. Further, it was suggested that based on the findings it may be appropriate to recommend a change to the statutory requirements for licensure detailed in B&PC 4202 to allow acceptance of either exam.

The committee took no action on this item.

- c. **FOR DISCUSSION and POSSIBLE ACTION: Summary of a Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**

Attachment 2

Relevant Statutes

Business and Professions Code Section 4231 requires pharmacists to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Business and Professions Code Section 4232 establishes the general content of courses.

Article 4 of Division 17 of Title 16, California Code of Regulations contains the relevant regulations implementing the statutes.

Background

At several prior meetings of the board or its committees, including the last two meetings 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.

Prior discussions have included the need to earn CE in emergency response, patient consultation or in maintaining control of a pharmacy's drug inventory.

At the October Board Meeting, the board directed that the committee continue its discussion about such a requirement.

Attachment 2 contains a summary of previous committee discussion on this issue as well as copies of the relevant statutes and regulations.

Committee Discussion/Action

The committee discussed the challenges in evaluating a course to ensure it is achieving the objective. The committee also discussed the possibility of breaking the CE requirement into required areas and discretionary subjects and suggested that staff could research providers and possible ways to implement.

MOTION: LICENSING COMMITTEE: Recommend that the board pursue specific content areas for continuing education. If the recommendation is approved, authorize staff to investigate implementation.

d. **FOR INFORMATION: Update on the Board's Efforts to Implement Title 16, California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists**

Background

Earlier this year, the board established new requirements for pharmacist renewal that were placed into CCR Section 1701. This regulation was approved by the Office of Administrative Law and is scheduled to take effect on December 7, 2010.

The regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

Beginning in December 2010, pharmacist renewals will be held if a licensee fails to complete the disclosure section on the renewal form.

However, the board was advised the beginning of November that due to the on-going fiscal crisis and hiring restrictions within State government, effective Monday, November 8, 2010, the California Department of Justice (DOJ) no longer has the resources to take phone calls or process follow-up inquiries from regulatory entities who have submitted a criminal offender record information search request through the DOJ or the Federal Bureau of Investigation (FBI). Because of this, implementation of the fingerprint requirements was delayed.

Committee Discussion/Action

The committee was advised that the board has been unsuccessful in obtaining the necessary changes to implement this provision because of its dependence on other agencies.

The committee did not take action on this item.

Recent Update

In late December 2010 the board was successful in achieving the necessary programming changes through the DOJ. Board staff anticipates the revised LiveScan form will be available for download from our web site the beginning of February 2011. We anticipate full implementation of this provision in June 2011. Affected pharmacists will be advised 60-90 days prior to renewal of the requirement.

e. **FOR DISCUSSION: Discussion of the California Hospital Association's Repopulation After Hospital Evacuation Guidelines and Checklist**

Attachment 3

The committee was advised that Executive Officer Herold served on a panel convened by the California Hospital Association to identify the components needing check off following the evacuation of the hospital but before the hospital can be "repopulated." The committee was provided a brief summary and was advised that with respect to the pharmacy, if called upon by the CDPH, the board will inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs.

Attachment 3 contains Hospital Repopulation after Evacuation Guidelines and Checklist, a transmittal memo from the CA Hospital Association and the actual repopulation guidelines.

The committee did not take action on this item.

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

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2010, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This process is done periodically to ensure the reliability of the examination. During such reviews the board encourages all qualified applicants to continue to schedule and take the CPJE exam. The greater the number of applicants who take the exam during this review period, the sooner results can be released.

This review was recently completed and results were released January 24, 2011.

Examination Development

Both Competency Committee workgroups met in the fall of 2010 to work on 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.

The committee did not take action on this report.

g. **FOR INFORMATION: Update on the Conversion to a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists in April 2011**

Attachment 4

Relevant Statutes

Business and Professions Code section 139, requires the board to complete an occupational analysis periodically which serves as the basis for the CPJE examination.

Background

Consistent with this requirement, in 2010 the competency committee developed a job analysis survey with the board's contracted psychometric firm. The results of this survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California.

Under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline, which was presented to the board at the April 2010 Board Meeting. After the board approved the revised content outline, the Competency Committee worked with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

The new outline and new sample questions will be posted on the board's Web site in early February 2011. Additionally, exam applicants will be sent a letter advising them of the change.

Attachment 4 contains a copy of the new content outline that will take effect April 1, 2011.

The committee did not take action on this item.

h. FOR INFORMATION: Licensing Statistics 2010/11

Attachment 5

Attachment 5 includes the licensing statistics for first and second quarter 2010/11.

i. FOR INFORMATION: Workload and Processing Statistics

Attachment 6

Last year the department established a new unit, Licensing through Job Creation. One of the products from this unit is workload and processing statistics for each program within the DCA. Although our board has collected and publicly reported this information for a very long time, not all board may have historically done so. The statistics generated internally vary a bit from those obtained by the department, but generally when looking at the information over a period of time, the statistics end up being pretty consistent.

Attachment 6 includes the most recent report from department.

j. FOR INFORMATION: Summary of the Meeting Held on December 2, 2010

Attachment 7

A summary of the meeting held on December 2, 2010 is provided in **Attachment 7**.

k. FOR INFORMATION: Second Quarterly Report on Licensing Committee Goals for 2010-11

Attachment 8

The second quarterly report on the Licensing Committee's goals is provided in **Attachment 8**.

Attachment 1

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



ISO 9001:2008 Certified
CMS Approved

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

The Provider's Choice

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, InsurNational 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

INTERPRETIVE GUIDE STANDARDS FOR ACCREDITATION

DMEPOS AND PHARMACY CORE: SECTIONS 100 - 600

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

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.

Evidence: Board Meeting Minutes
Response to Interviews
Reports to ACHC
Federal Agency and State Licensure Agency Report(s) and/or Inspections from authorized regulatory and accrediting bodies

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.

Evidence: Written Policies and Procedures
Written Description of Services
Marketing Materials to include Electronic Media
Documents that include Service Descriptions

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

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/criteria.

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.

Evidence: Written Policies and Procedures
Personnel Files

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.

Evidence: Written Policies and Procedures
Personnel Files

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.

Evidence: Personnel Files
Response to Interviews

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.

Evidence: Organization Documentation
Personnel Files
Response to Interviews

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 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

utilized by the organization.

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.

Evidence: Orientation Records
 In-Service Education Records
 Personnel Files
 Response to Interviews

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.

Evidence: Observation

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.

Evidence: Written Policies and Procedures

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 work place safety measures. Safety measures address building safety and security, staff safety and security, equipment safety, client/patient/family safety and security and home safety.

Evidence: Orientation Records
 In-service Records
 Response to Interviews

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

INTERPRETIVE GUIDE

STANDARDS FOR ACCREDITATION

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
Responses 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.

Evidence: Written Policies and Procedures
 Patient Record Reviews

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 criteria 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., elastomeric, 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 BCS/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) <797> Pharmaceutical Compounding – Sterile Preparations and (5) pharmacy regulations for any state into which medications are dispensed.

Evidence: Observation
Response to Interviews

INTERPRETIVE GUIDE

STANDARDS FOR ACCREDITATION

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.

Evidence: Observation
 In-service Education Files/Logs
 Inspection Logs
 Response to Interviews

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/coordinated 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 its 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 policies 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 providers 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 a 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 result 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 re-issued 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

Virginia Herold Executive Director
1625 North Market Blvd suite N219
Sacramento, Ca 95834

12/30/2010

Ms. Herold;

In follow up to the licensure board meeting held in December, I am submitting to you the information requested by the board. I want to thank the board for recognizing our Pharmacy Accreditation Program. This type of recognition is important to ACHC as we feel that our accreditation program strives to improve the quality of healthcare.

- ACHC accredits 19 parent pharmacy companies in California with a total of 54 locations.
- ACHC accredits 194 parent pharmacy companies throughout the United States with a total of 603 locations.
- ACHC has a total of 3075 parent companies accredited for all scopes of services provided, with a total of 11,282 locations throughout the United States. Of these 1079 (36%) parent locations were deferred on their initial survey.
- ACHC has denied 218 companies however if a company was denied and re-applied and then accredited their numbers would not be reflected in the 218 total.

In reviewing the above summary, the following explanations will help with the information provided.

1. ACHC recognizes parent companies as having more than one location. These additional locations may or may not be located in the same state as the parent company.
2. Most companies that received a deferral status were granted accreditation after approval of a Plan of Correction (POC)
3. Denied companies, in most cases, reapply for accreditation. After a new survey a majority are accredited
4. ACHC did not make a distinction between Compounding (Infusion) pharmacies and specialty until the early part on 2010. The data that you are reviewing includes all pharmacies that do any type of compounding (infusion) except for creams or would be classified as a specialty pharmacy by the California Board of Pharmacy definition outlined in their new standards.

. If you need any addition information please feel free to contact me at 919-785-1214.

Respectfully submitted

Timothy Safley
Clinical manager HME, Pharmacy, Sleep Manager
ACHC

Community Health Accreditation Program (CHAP)



COMMUNITY HEALTH ACCREDITATION PROGRAM

1275 K Street, NW • Suite 800 • Washington, DC 20005 • tel: 202.862.3413 • fax: 202.862.3419 • www.chapinc.org

March 26, 2010

Debbie Anderson

Site Licensing Manager

California State Board of Pharmacy

1625 N. Market Blvd. Suite N219

Sacramento, CA 95834

RECEIVED BY CALIF.
BOARD OF PHARMACY
2010 APR -6 AM 8:36

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 or 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.

CHAP 3/99
Rev. 9/18/02
Rev. 9/26/06
Rev. 11/7/07
Rev. 2/23/2009
Rev. 5.28.2009
Rev. 9.22.2009
Rev. 11.16.2009

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 to at various times in the accreditation cycle. The following table illustrates types of visits and related information.

Visit Type	Timing	Standards Reviewed	CARES Visit Loading	CMS Docs (1572, etc.)	ASSURE/DMEPOS Database?	CMS Schedule	CHAP Docs
Comprehensive							
Comprehensive	Initially and Every 36 months	Core Service Specific	All CORE and Service Specific Standards	Standard Survey	Yes	Yes	POC Accred Letter
Core Only (Florida)	1-4 months after Self Study submitted	Core	Modified	No	No	No	POC Accred Letter
Follow-Up							
a. COMPLAINT	PRN	Core Service Specific	Modified CORE	Only if IJ	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

Visit Type	Timing	Standards Reviewed	CARES Visit Loading	CMS Docs (1572, etc.)	ASSURE/DMEPOS Databases?	CMS Schedule	CHAP Docs
e. STATE MANDATED ANNUAL (NEW JERSEY)	12 months after last scheduled site visit	Core Private Duty	Modified	New Jersey specific	No	No	POC Accred Letter
f. BOR REQUIRED FOCUS	6 months or 12 months after last site visit date	Former Required Actions POC with Agency Response	Prior Required Actions	No	No	No	POC Accred Letter
g. CHAP VALIDATION SURVEYS (INTER-RATER RELIABILITY)		UNDER DEVELOPMENT					
h. CONDITION LEVEL DEFICIENCY FOLLOW UP	< 90 days after end of visit with deficient finding	Standards and conditions cited	Modified	Yes	Yes	No	POC Accred Letter
i. HOSPICE ADDING IN-PT UNIT							
j. CHANGE OF OWNERSHIP							

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

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The Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800
Washington, DC 20005

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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.

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

Main Sources of Evidence

Substantiation of Findings

- D = Documents
- I = Interviews
- O = Observations
- S = Surveys

- 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 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:

ADA Americans with Disabilities Act
Admin. Administration

P&Ps Policy(ies) and Procedure(s)

CDC Centers for Disease Control
and Prevention

TO Table of Organization

TB Tuberculosis

FDA Federal Drug Administration

GB Governing Board

HBV Hepatitis B Vaccine

MC Medicare

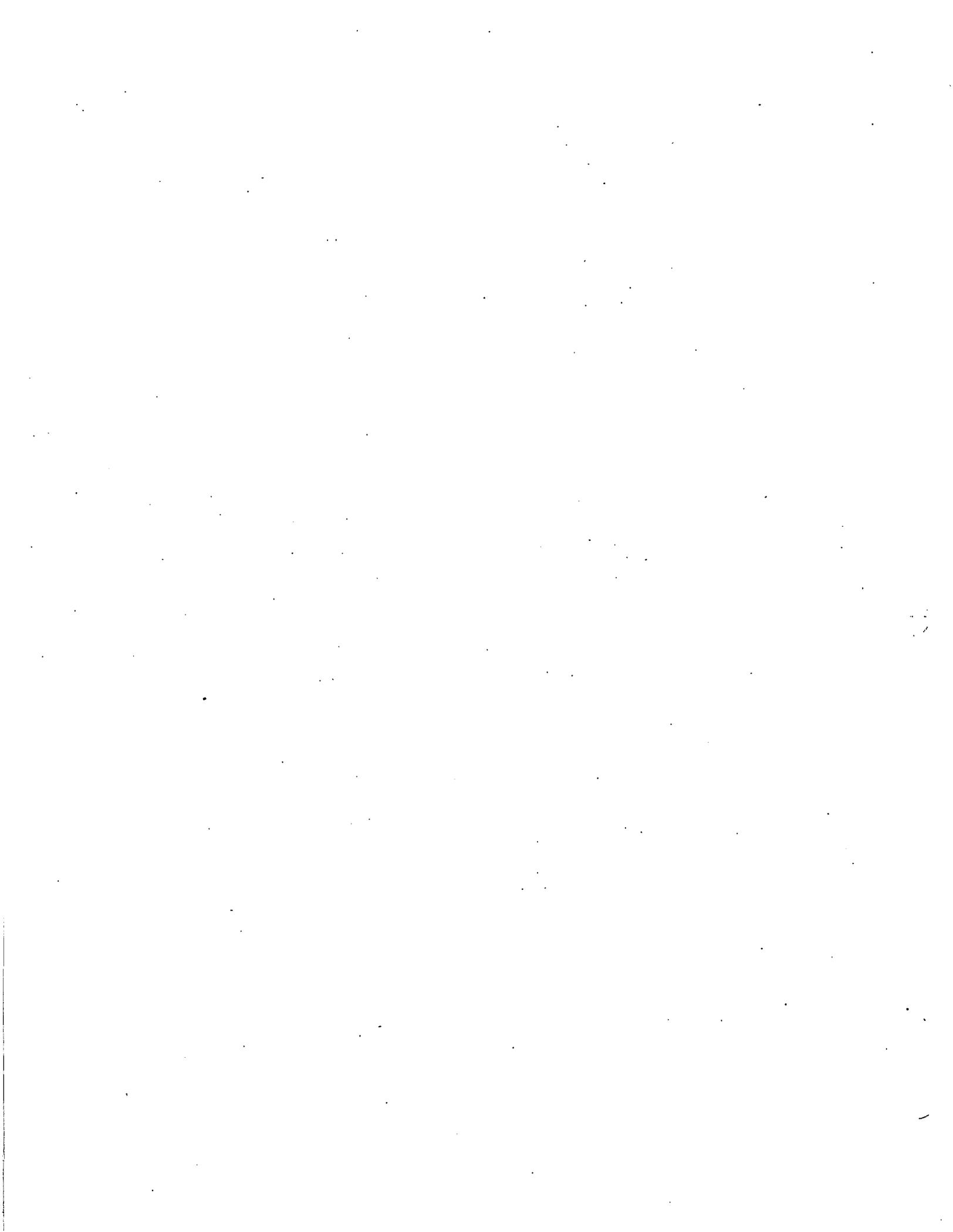
MD Medicaid

MDA Medical Device Act

Mgmt. Management

N.B. "Note Well"

OSHA Occupational Safety and Health Act



CI.

CI.

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

LEGEND:

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

CI.1

- | |
|--|
| <p>D: Current Mission statement includes a consumer focus and orientation to quality. (CI.1)</p> <p>D: Consumers are defined as individuals, groups and communities. (CI.1)</p> <p>D: Governing body minutes document actions taken on the Mission:</p> <ul style="list-style-type: none">a) Review and approval at least every 36 monthsb) Revisions and updates as applicable <p>(CI.1b)</p> |
|--|

CI.1 Published mission statements clearly identify a commitment to providing high quality services and products which address consumer needs as an organizational priority.

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

CI.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
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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 IHH for a full text of the regulations and a cross-walk.*
- 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.2 The organization has the structure and functional mechanisms necessary to support and accomplish its stated mission.

- 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 minimum of five (5) years or consistent with state regulations.

LEGEND:

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

CI.3

- D:** A current organizational chart reflects lines of authority and accountability for all personnel. (CI.3a)
- D:** Amendments to the organizational chart are documented as applicable. (CI.3b)
- I:** Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (CI.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.

CI.3 Intra-organizational relationships are clearly defined.

CI.3a A current organizational chart delineates the lines of authority and accountability of all personnel.

CI.3b The organizational chart is reviewed and changed as needed.

CI.3c Personnel understand and use the organizational structure as outlined in the organizational chart.

LEGEND:

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

CI.4

- D:** Current job descriptions are on file for administrative and management positions. (CI.4a, b)
- D:** 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.*
- D:** Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)
- I:** Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)
- I:** 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 cross-walk.

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.

CI.4 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

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

CI.5

- I:** Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.5a)
- D:** Administrative policies and procedures address the areas delineated in CI.5b.
- D:** 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.5b)
- D:** Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.5c.
- D:** Personnel policies address the 9 elements of CI.5d.

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), 484.52, 484.52(b), 484.55. 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 418.50(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

LEGEND:

- D - DOCUMENTATION
- I - INTERVIEW
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- S - SURVEY

CI.5 (Continued)

- D:** Written TB Exposure Control Plan includes the elements in CI.5e.
- D:** Written policy and procedure define the requirements of Medical Device Act reporting. (CI.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. (CI.5f)
- D:** Written infection control policies and procedures include the elements in CI.5g.

CI.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

CI.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

CI.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

LEGEND:

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

CI.5 (Continued)

- D:** Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (CI.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. (CI.5h)
- D:** Written policy and procedure and local/state/federal regulations dictate the secure retention of all types of clinical records. (CI.5h)
- D:** Written policy and procedure details the process for release of information. (CI.5h)
- I:** Records administrator or other designated party describes adherence to policy and procedure. (CI.5h)
- I:** Staff describe process for accessing policies and procedures. (CI.5i)

- 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.5h 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.5i Staff members have access to policies and procedures.

LEGEND:

D - DOCUMENTATION

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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

CI.6a Language specific written materials, as necessary and appropriate, are available for distribution to client/families.

CI.6b Interpretive services are provided, as indicated and necessary, to ensure accurate communication between the client/family/caregiver and other types of health services personnel.

LEGEND:

- D - DOCUMENTATION
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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.

LEGEND:

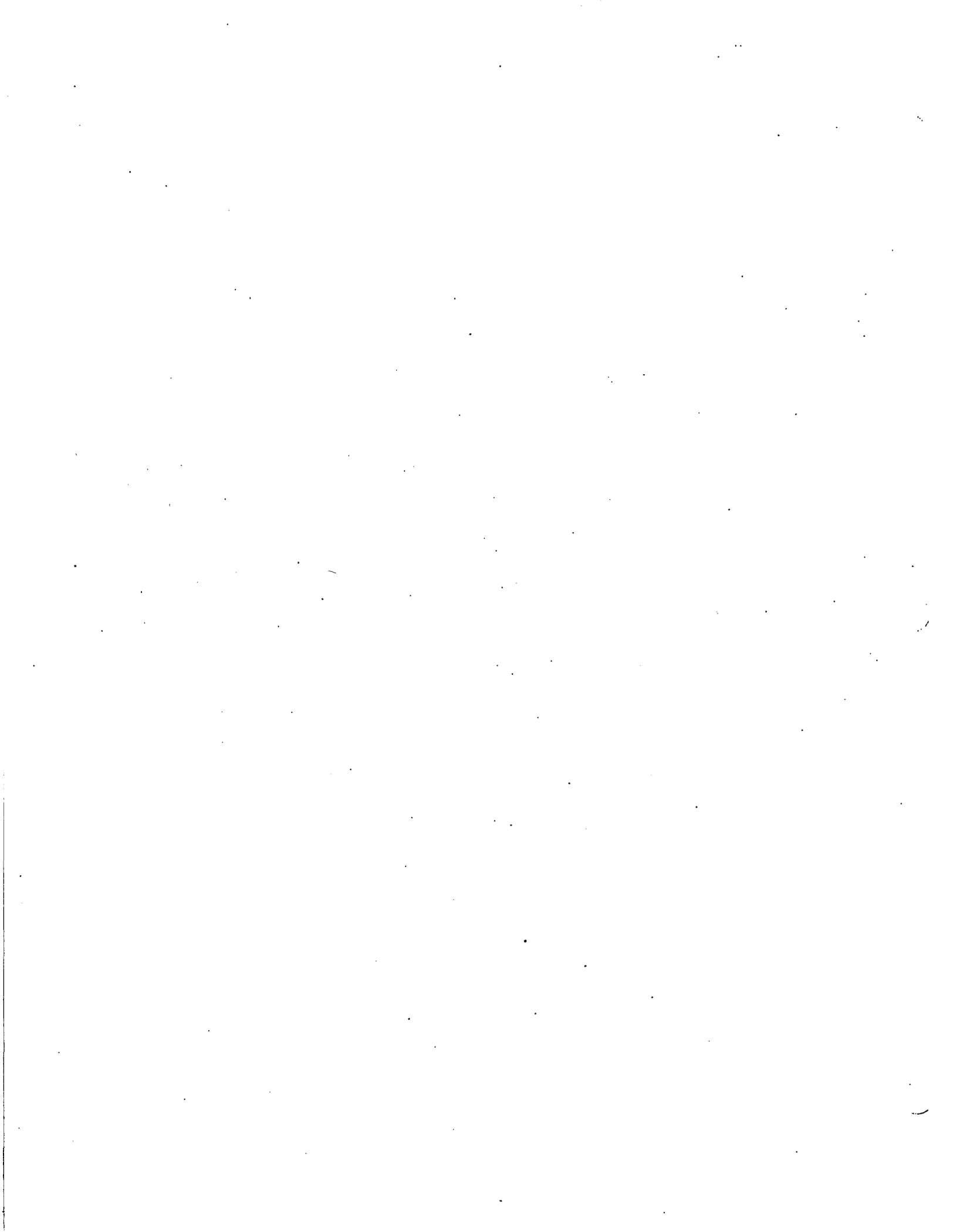
- D - DOCUMENTATION
- I - INTERVIEW
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- S - SURVEY

CI.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. (CI.8a)
- D:** Policy and procedure establish the parameters for research initiatives as applicable. (CI.8b)
- D:** Current research activities as applicable ensure compliance with CI.8a,b, c, d.
- I:** Administrative/management personnel describe current research initiatives as applicable. (CI.8c)
- I:** Staff describes use of research knowledge which was integrated into practice as applicable. (CI.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**

LEGEND:

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

CII.1

- D:** Current Public Disclosure Policy addresses applicable elements of CII.1a.
- 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.1c)

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 I HH for a full text of the regulations and a cross-walk.

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.

LEGEND:

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

CII.2

- 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.**

LEGEND:

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

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.

LEGEND:

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

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.

LEGEND:

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

CII.5

- 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 cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.74, 418.74(a,b). See Appendix 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.

LEGEND:

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

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
 CII.7

- D:** Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (CII.7a)
- D:** Written plans define parameters for exposure control, adherence to standard precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (CII.7b)
- D:** Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: (CII.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: (CII.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. (CII.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. (CII.7f)
- D:** Education and training records document compliance with training requirements. (CII.7g)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c). 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 418.50(b), 418.100 (c), 418.100(i). See Appendix IH 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

CII.8

- D:** Examples of complaint documentation logs. (CII.8a)
- D:** Formal documentation of investigative findings and reports as applicable. (CII.8a)
- D:** Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CII.8b)
- I:** Staff describes an understanding of the complaint process. (CII.8c)

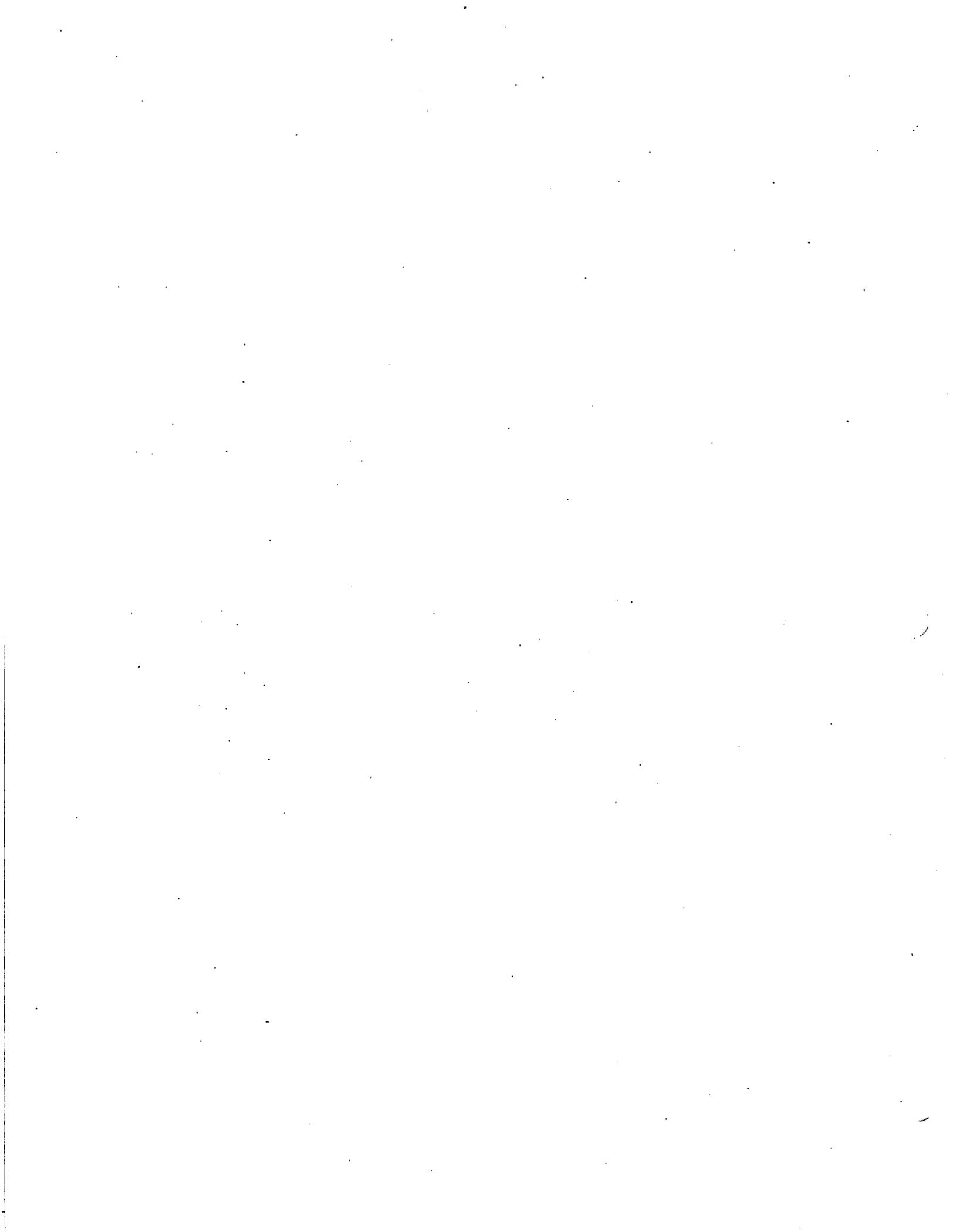
Note: The Medicare Certified home health agency must comply with CFR 484.10(b). See Appendix I HH for a full text of the regulations and a cross-walk.

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**

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

CIII.1

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 cross-walk.

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.

CIII.1 The organization has adequate and appropriate human resources to meet caseload and workload demands.

- CIII.1a** A non-discriminatory recruitment and selection process, as defined in policy and procedure, is adhered to.
- CIII.1b** Personnel are employed and assigned responsibilities commensurate with their education and experience.
- CIII.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.
- CIII.1d** Employee turnover rates are monitored tracked and trended, as applicable.
- CIII.1e** The opportunity for exit conferences are offered to terminating employees, are documented and trended, as applicable.
- CIII.1f** Personnel policies/conditions of employment are provided to employees at the time of hire and thereafter as updates/revisions are needed.
- CIII.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)
- CIII.1h** Specified personnel documents and employee health reports may be retained in separate files per organization policy.

LEGEND:

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

CIII.1 (Continued)

- D:** Annual evaluation form addresses elements of CIII.1i as applicable to the job category.
- I:** Sample of employee and supervisory staff personnel records confirms adherence to the annual evaluation process. (CIII.1i, 1j)
- 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. (CIII.1k)
- I:** Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CIII.1k)
- I:** Staff assigned to a new job classification describe their orientation to the new responsibilities. (CIII.1k)
- I:** Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CIII.1l)
- 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. (CIII.1l)
- 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. (CIII.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.

LEGEND:

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

CHL.2

D: A review of a randomized sample of written contracts for the provision of care, services and/or products validates adherence to CHL.2, a, b.

I: Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CHL.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 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**

LEGEND:

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

CHIL3

- D:** Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CHIL3a)
- I:** The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CHIL3b)
- D:** Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CHIL3c)
- D:** The organization has a current operating budget and capital expenditure plan. (CHIL3d)
- D:** Financial, statistical and productivity reports are used to facilitate oversight of the organization's operations. (CHIL3e)
- I:** The chief financial manager describes the use of financial, statistical or productivity reports. (CHIL3e)
- I:** The chief financial manager validates the adequacy of insurance coverage. (CHIL3f)
- 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. (CHIL3g)

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.

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.

CIIL.3 The organization's sources of financial support are managed and monitored on an ongoing basis to ensure the availability of adequate funding.

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

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

CIIL.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.

CIIL.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.

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

CIIL.3f Adequate insurance coverage is maintained.

CIIL.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.

CIII.4 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.

CIII.4a The financial reporting system produces detailed data regarding actual transactions specific to care, services and products provided by each program including site/ location activity.

CIII.4b Periodic financial statements contain key indicators and show a reasonable match between revenue and expense line items.

CIII.4c 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.**

CIII.4d Reimbursable services are billed on a timely basis in accordance with designated fee structures and are monitored, tracked and aged.

CIII.4e 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.

CH.5 Physical facilities are adequate to support the operations.

CH.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.

LEGEND:

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

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.



CIV.

CIV.

**THE ORGANIZATION
IS POSITIONED FOR
LONG TERM VIABILITY**

LEGEND:

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

CIV.1

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 cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66. See Appendix IH 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

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PHARMACY

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PHARMACY

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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.

PHARMACY

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

PHARMACY

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.

DI.

**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)

PHARMACY

DI.1

DI.1	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.
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DI.1a **The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.**

DI.1b **The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.**

PHARMACY

LEGEND:

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

DI.2

- D:** Required County/State/Federal licenses, authority documents, and Medicare/Medicaid/reimbursement certification (if applicable) are current as required. (DI.2a)

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

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

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

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

- D:** Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DI.2c)

PHARMACY

DI.2

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.

PHARMACY

LEGEND:

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

DI.2 cont'd

- I: 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.**

PHARMACY

LEGEND:

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

DL.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. (DL.3a,3b)

PHARMACY

DL3

DL3 Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.

DL3a A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.

DL3b The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.

PHARMACY

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

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.

PHARMACY

DI.4

DI.4 Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.

DI.4a 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.

DI.4b A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.

DI.4c 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, in-service 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

DI.4d 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)

PHARMACY

DI.5

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

DI.5 cont'd

- D:** Pharmacy clinical policies and procedures at a minimum address items 1-6. (DI.5d)
- D:** Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DI.5e)
- D:** Written policy is available for first dose drug. (DI.5f)

DI.5d 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

DI.5e 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

DI.5f 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.

PHARMACY

LEGEND:

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

DI.6

- D: Meeting minutes document discussions of and actions taken by the group, as applicable. (DI.6a)
- I & O: Staff demonstrates knowledgeable of and compliance with reimbursement and regulatory guidelines. (DI.6b)

PHARMACY

DI.6

DI.6 The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.

DI.6a 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

DI.6b Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.

PHARMACY

LEGEND:

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

DI.7

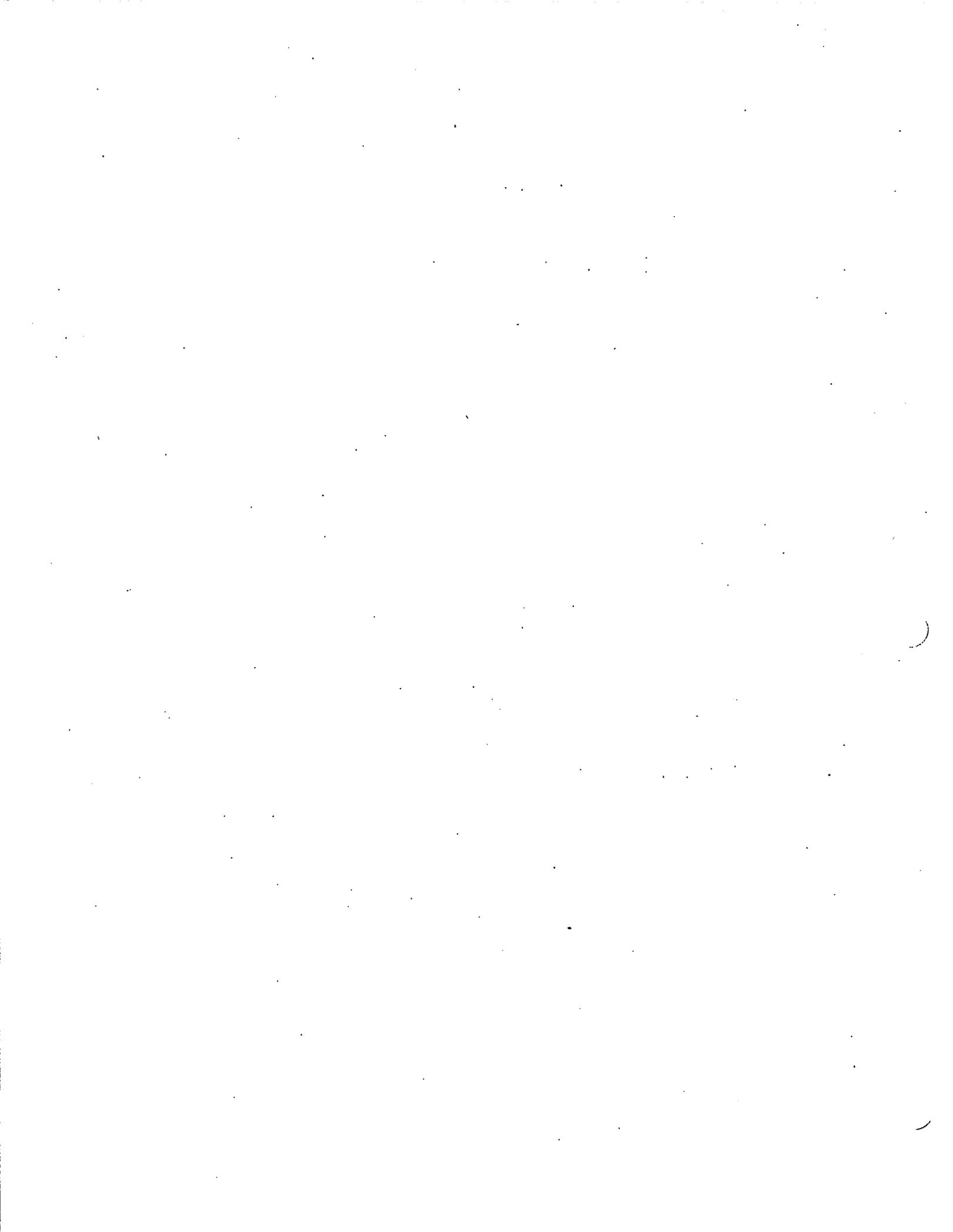
- I:** Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigative studies. (DI.7a)
- D:** Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DI.7b)
- D & I:** Documents and interviews validate that current research initiatives exist as applicable. (DI.7c)
- D & I:** Pharmacy employees publish research findings as applicable. (DI.7d)

PHARMACY

DI.7

DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.
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- 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.



DII.

**THE PHARMACY ORGANIZATION CONSISTENTLY
PROVIDES HIGH QUALITY
PRODUCTS AND SERVICES**

PHARMACY

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)

PHARMACY

DII.1

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.

PHARMACY

LEGEND:

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

DII.2

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

PHARMACY

DII.2

DII.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.

DII.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.

DII.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.

PHARMACY

LEGEND:

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

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 confirms 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)

PHARMACY

DII.2c

DII.2c The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.

DII.2d 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

DII.2e 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.

DII.2f 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.

PHARMACY

LEGEND:

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

DII.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)

PHARMACY

DII.3

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

PHARMACY

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

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)

Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4)

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

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)

PHARMACY

DII.4

DII.4 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.

PHARMACY

LEGEND:

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

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)

PHARMACY

DII.5

DII.5 The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.

DII.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

DII.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 DII.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

DII.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

DII.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

PHARMACY

LEGEND:

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

DII.5 cont'd

- 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)

PHARMACY

DII.5e

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

PHARMACY

LEGEND:

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

DII.6

- 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. a– h. (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)

PHARMACY

DII.6

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.

PHARMACY

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

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.**

PHARMACY

LEGEND:

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

DII.7

- 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)

PHARMACY

DII.7

DII.7 The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.

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.

PHARMACY

LEGEND:

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

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)

PHARMACY

DII.8

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

PHARMACY

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)

PHARMACY

DII.8e

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

PHARMACY

LEGEND:

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

S - SURVEY

DII.9

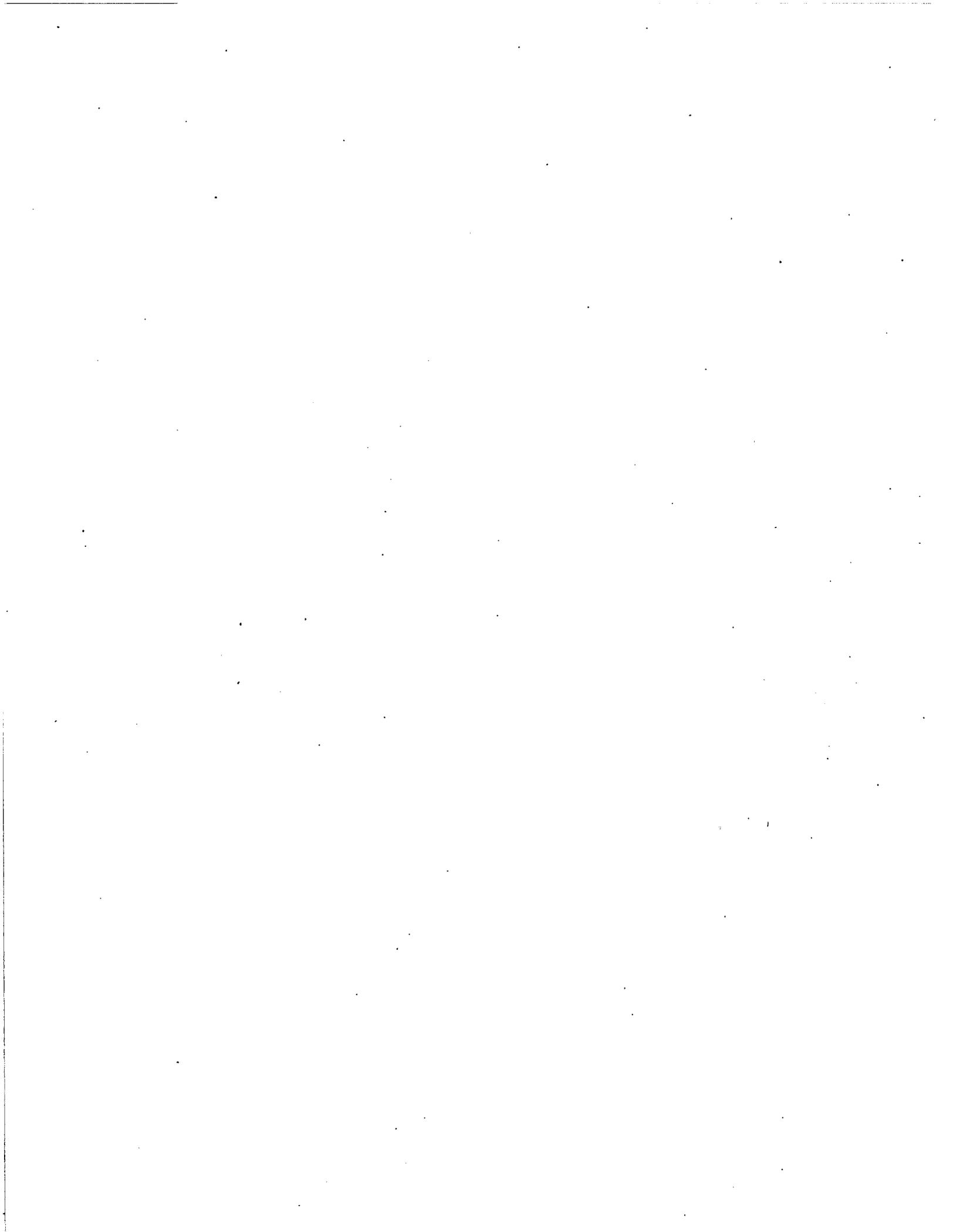
D: Documentation validates that the complaint process includes elements 1-9. (DII.9a)

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



DIII.

**THE PHARMACY ORGANIZATION HAS ADEQUATE
HUMAN, FINANCIAL, AND PHYSICAL
RESOURCES, WHICH ARE EFFECTIVELY
ORGANIZED TO ACCOMPLISH
ITS STATED MISSION**

PHARMACY

LEGEND:

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

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)

PHARMACY

DIII.1

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

PHARMACY

LEGEND:

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

DIII.1 cont'd

D: An orientation plan is available and includes elements 1-5. (DIII.1e)

D & I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)

D: 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.

D: Records show documentation of organization's provision of annual in-service program and pharmacist's attendance at the in-service. (DIII.1h)

PHARMACY

DIII.1e

DIII.1e 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

DIII.1f 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.

DIII.1g Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.

DIII.1h The organization provides a minimum of one medication safety in-service annually.

PHARMACY

LEGEND:

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

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)

PHARMACY

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 CIII.2a-b and, in addition, the following specific responsibilities:

- 1) Which organization has the authority to accept and terminate client services
- 2) Services provided under contract must be in compliance with professional standards
- 3) The manner, in which products and services will be controlled, coordinated and evaluated
- 4) Designation of responsibilities for orientation

DIII.2b Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:

- 1) Who is responsible for teaching the client about pharmaceuticals
- 2) Assurance that personnel meet the pharmacy program's educational and training requirements
- 3) Maintenance of current licensure and certification where required
- 4) On site supervision of pharmacy personnel
- 5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"
- 6) Time frames for response to new referrals
- 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 CIII.2 a-b, DIII.2a and, in addition, include the provisions for:

- 1) Ensuring clean and safe transport of equipment and supplies
- 2) Timely delivery of products and supplies
- 3) Setting up equipment in client's homes, where appropriate
- 4) Adequately trained delivery personnel
- 5) Client education, where appropriate
- 6) Appropriate documentation

PHARMACY

LEGEND:

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

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)

PHARMACY

DIII.3

DIII.3 **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 short falls 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.**

PHARMACY

LEGEND:

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

DIII.4

O: Observation of the physical facility validates that elements 1-7 are in evidence and in conformance with state/federal requirements. (DIII.4a)

D: Written policies specify elements 1-5. (DIII.4b)

O: 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)*

D,I&O: Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)

O: Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)

D&O: 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)

DIII.4 The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.

DIII.4a 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/styrofoam

DIII.4b 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.

DIII.4c 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.

DIII.4d 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.

DIII.4e 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

PHARMACY

LEGEND:

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

DIII.4 cont'd

- 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)

PHARMACY

DIII.4f

DIII.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.

DIII.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.

DIII.4h Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.

DIII.4i Injectables prepared from non-sterile powders are:

- 1) Dissolved in sterile solution for injection
- 2) Filtered through a 0.2 micron filter.

DIII.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

DIII.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

DIII.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

PHARMACY

LEGEND:

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

DIII.5

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.

PHARMACY

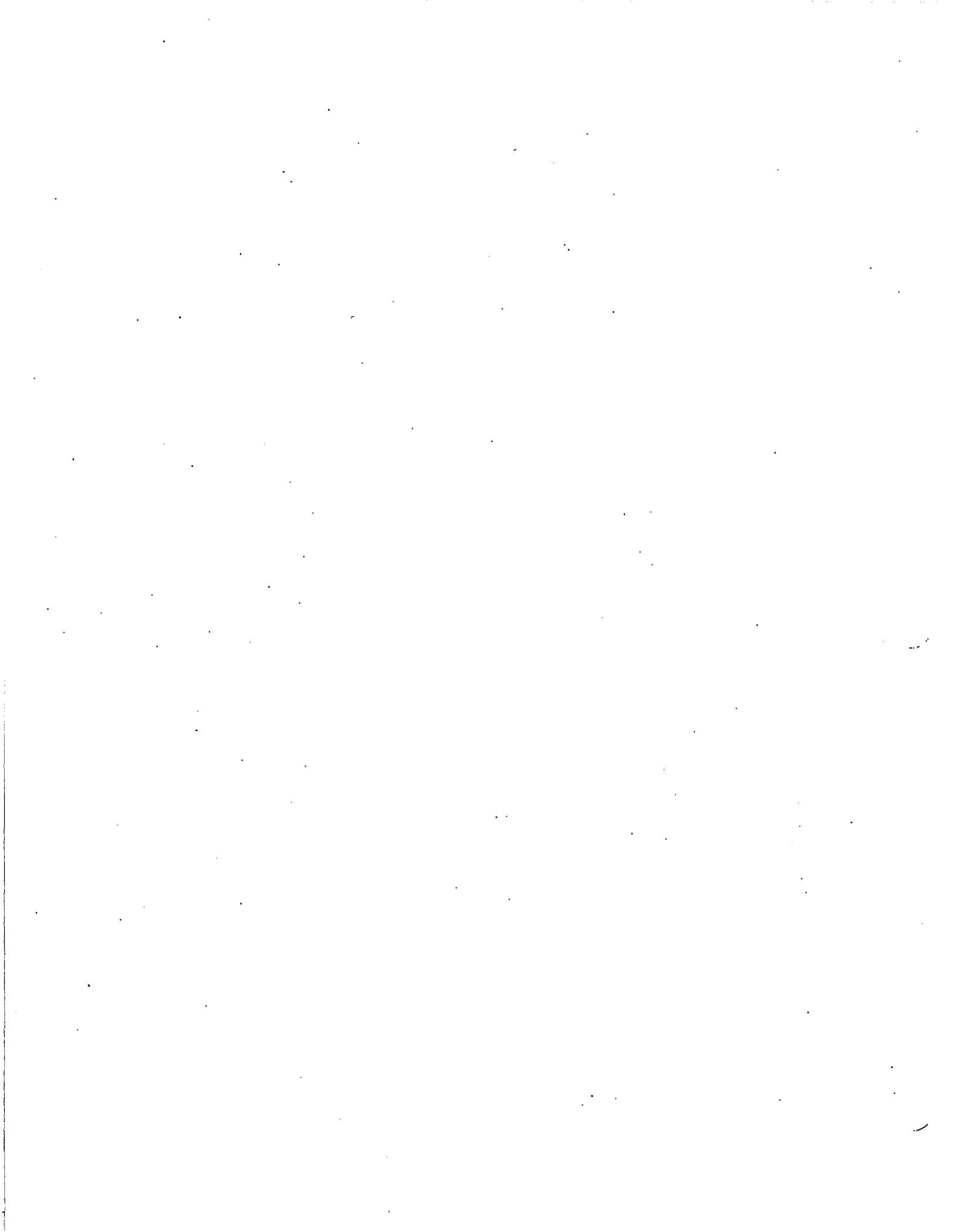
DIII.5

DIII.5 An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.

DIII.5a 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.

DIII.5b The organization participates in a benchmarking system.

- 1) Benchmark data are consistent with organizationally defined goals and objectives
- 2) Benchmark collected data, when available, are measured against data from other organizations



DIV.

**THE PHARMACY ORGANIZATION
IS POSITIONED FOR
LONG TERM VIABILITY**

PHARMACY

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)

PHARMACY

DIV.1

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.**

PHARMACY

LEGEND:

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

DIV.2

- 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. (DIV.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)

PHARMACY

DIV.2

DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.
-------	--

DIV.2a 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.

DIV.2b Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.

DIV.2c Pricing of products and services is routinely evaluated.

DIV.2d Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.

PHARMACY

LEGEND:

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

DIV.3

O: Innovations have been developed and implemented.
(DIV.3)

PHARMACY

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 mannerAccept 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

1. Demonstrated preparedness to work as a member of team in conducting the site visit.	5	4	3	2	1	0
2. Demonstrated introductory knowledge of CHAP standards specific to the site visit.	5	4	3	2	1	0
3. Accurately interpreted and applied State and Federal Regulatory requirements specific to the site visit.	5	4	3	2	1	0
4. Demonstrated accuracy, appropriateness and objectivity in collecting, clarifying, quantifying, interpreting, and reporting data.	5	4	3	2	1	0
5. Used appropriate decision making processes.	5	4	3	2	1	0
6. Developed relationships with co-team members and agency staff that facilitated the site visit process.	5	4	3	2	1	0
7. Carried out responsibilities related to the site visit in an organized and professional manner	5	4	3	2	1	0
8. Demonstrated effective time management skills.	5	4	3	2	1	0
9. Was a professional role model for CHAP.	5	4	3	2	1	0
10. Employed effective interpersonal skills when dealing with patients, families, staff, and administrative personnel.	5	4	3	2	1	0
11. Articulated findings in a clear, succinct and professional manner.	5	4	3	2	1	0
12. Provided valuable consultation to staff and administrative personnel.	5	4	3	2	1	0

Strengths: _____



Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800 Washington, DC 20005

Performance Evaluation For Site Visitors

- ✓ Self Evaluation
- ✓ 90 Day Evaluation
- ✓ Annual Evaluation
- ✓ Interim Evaluation

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:

Performance Planning (ongoing):	Managing Daily Performance (ongoing):	Performance Summary:
<ul style="list-style-type: none"> • expected results • expected behaviors • individual development planning 	<ul style="list-style-type: none"> • constructive feedback • coaching • recognition • removing obstacles • discipline when necessary • documentation 	<ul style="list-style-type: none"> • 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 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 in 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:

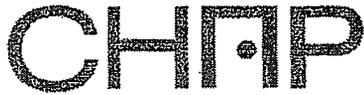
- Customer Satisfaction (both internal and external)
- Job Acumen
- Results
- Team Success
- Professional Development (of self and others)

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



Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800 Washington, DC 20005

Performance Evaluation For Site Visitors

Type of Review: Choose an item.

		Employment Status
Employee:	Click here to enter text.	
Job Title:	Site Visitor	
Supervisor:	Click here to enter text.	
Period of Performance:	Starting Date:	Ending Date:
	Click here to enter a date.	Click here to enter a date.
		Next Review Date:
		Click here to enter a date.

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.

LEVEL OF PERFORMANCE	RATING
<p>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.</p>	E
<p>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.</p>	C
<p>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.</p>	S
<p>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.</p>	N
<p>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.</p>	U

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.

Customer Satisfaction	Rating:
<ul style="list-style-type: none"> • Takes initiative to meet agency needs • Responds to internal and external requests in a timely manner • Proactively recognizes potential problems and takes action to resolve them • Is recognized positively by internal and external customers 	Select Rating
Evaluation of Achievement	
Job Acumen	Rating:
<ul style="list-style-type: none"> • Performs all essential functions of the job accurately • Develops and maintains expert level of knowledge about Standards of Excellence • Develops and maintains expert level of knowledge about CMS Conditions of Participation and/or Quality and Supplier standards • Interprets and analyzes standards and evidence consistently and accurately • Provides applicant and accredited organization education on performance improvement 	Select Rating
Evaluation of Achievement	
Results	Rating:
<ul style="list-style-type: none"> • Submits required Site Visit documentation within 2 Business days • CARES documentation is accurate and complete. Includes a Summary and Accreditation Recommendation and as per documentation guidelines, organization strengths and challenges • Site visits are conducted effectively • Evidence is fact based and relevant • Written documentation is clear and substantiates cited evidence • CMS documents are complete and accurate 	Select Rating
Evaluation of Achievement	
Team Success	Rating:
<ul style="list-style-type: none"> • Builds positive relationships and team morale • Asks for and offers help • Sets a good example and motivates others • Coordinates and collaborates with all team members • Provides updated license, as required, and consulting detail timely • Actively avoids any appearance of Conflict of Interest 	Select Rating
Evaluation of Achievement	

Professional Development	Rating
<ul style="list-style-type: none"> • Takes the initiative to share professional knowledge and information with others • Formally or informally mentors other employees • Seeks out opportunities to improve expertise (i.e., keep up to date w/ regulations, read books/trade magazines, etc., attend training, seminars, meetings) • Attends and participates in CHAP teleconferences and Mandatory Meetings • Meets requirement for 8 hours of continuing education in addition to attending CHAP annual meeting for 20 hours of education 	Select Rating
Evaluation of Achievement	

SECTION II - COMPETENCIES AND MANAGEMENT SKILLS - Evaluate the extent to which competencies and/or management skills were demonstrated in achieving desired results.

Competencies					
Accepting Supervision	Select Rating	Meeting Schedules and Deadlines	Select Rating		
Accuracy	Select Rating	Motivating Others	Select Rating		
Attention to Detail	Select Rating	Planning and Organizing	Select Rating		
Authority and Presence	Select Rating	Positive Attitude	Select Rating		
Business Acumen	Select Rating	Problem Solving and Innovation	Select Rating		
Clear Written and Verbal Communication	Select Rating	Professionally Represents CHAP	Select Rating		
Conducting Entrance/Exit Conferences	Select Rating	Providing Constructive Feedback	Select Rating		
Dependability	Select Rating	Quality of Work	Select Rating		
Development/Mentoring	Select Rating	Recognizing Performance	Select Rating		
Flexibility and Adaptability	Select Rating	Supporting Organizational Goals	Select Rating		
Integrity	Select Rating	Taking Initiative	Select Rating		
Judgment / Decision Making	Select Rating	Team Building	Select Rating		
Leadership	Select Rating	Treating Others With Respect	Select Rating		
Managing Change	Select Rating	Working Independently	Select Rating		
<i>Fill in the number of times the individual received each rating.</i>					
Exceptional	Commendable	Solid	Needs Improvement	Unacceptable	Total

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.

GOAL ACCOMPLISHMENTS		
Goals For Past Year	Evaluation of Achievement	Rating
		Select Rating
		Select Rating
		Select Rating

GOAL DEVELOPMENT	
Goals For Upcoming Year	Action Plan

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.

EVALUATION SUMMARY		
<i>Please transfer your ratings to the left side and then choose the overall ratings on the right side by checking the appropriate box.</i>		
EVALUATION COMPONENTS		OVERALL EVALUATION
Customer Satisfaction	Select Rating	Select Rating
Job Acumen	Select Rating	
Results	Select Rating	
Team Success	Select Rating	
Professional Development	Select Rating	
Competencies	Select Rating	
Goal Accomplishment	Select Rating	
SIGNATURES		
<i>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.</i>		
Employee: (all reviews)		Date:
Supervisor: (all reviews)		Date:
Chief Operating Officer: (annual review only)		Date:
Human Resources: (annual review only)		Date:
EMPLOYEE COMMENTS (optional)		

*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!*



COMMUNITY HEALTH ACCREDITATION PROGRAM

1275 K Street, NW • Suite 800 • Washington, DC 20005 • tel: 202.862.3413 • fax: 202.862.3419 • www.chapinc.org

January 6, 2011

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

Dear Ms. Herold,

Subsequent to the meeting with the Licensing Committee of the California Board of Pharmacy to renew approval for CHAP for California Sterile compounding, we have reviewed in depth the files of the CHAP accredited pharmacies which received a validation survey from the California Board of Pharmacy. These are the relevant facts:

Pharmaco dba Premier Infusion Care PTAN 5136660001

2341 West 205th Street Unit 113
Torrance, CA 90501

Original contract with CHAP for accreditation 5/10/2004

Initial accreditation 11/15/2006-11/14/2009

Renewal of accreditation contract 8/25/2009

Most recent site visit: 2/22/2010-2/23/2010

Process: All CHAP Pharmacy Standards of Excellence were assessed through inspection, interview, and documentation review, including 10 client record reviews, 2 client interviews, 10 staff personnel record reviews

Findings: No findings of deficiencies with Pharmacy standards; one deficiency cited related to the administrative requirements built into contracts. A Plan of Correction was submitted for this deficiency and accepted on 3/5/2010. Premier received a final determination of accreditation with Required Action effective 11/15/2009-11/14/2012

Site Visitor: David Martin BSc Pharmacy, Pharm. D., FACN, CNS, FASCP Hire date with CHAP 12/18/2005 resume attached

Atwell Home Care, Inc. dba Apex Infusion Pharmacy PTAN 573212001

3299 East Hill Street

Signal Hill, CA 90755

Original contract with CHAP for accreditation 8/7/2006

Initial accreditation 10/18/2006-10/17/2009

Renewal of accreditation contract 10/9/2009

Most recent site visit: 3/25/2010-3/26/2010

Process: All CHAP Pharmacy Standards of Excellence were assessed through inspection, interview, and documentation review, including 12 client record reviews, 4 client interviews, 5 staff personnel record reviews

Findings: 1 pharmacy standard deficiency (all pharmaceuticals are dispensed according to the prescription of a duly licensed provider-all IV infusions were prescribed; heparin and saline flushes did not have specific prescriptions), and two deficiencies related to CORE standards- CHAP hotline not provided to clients who might have a complaint, and no dedicated space for the receipt, storage, and cleaning of contaminated equipment. A Plan of Correction was submitted for these deficiencies and was accepted on 4/15/2010.

Site Visitor: Richard Daniels BSc Pharmacy, Pharm. D. Hire date with CHAP 4/21/2003 resume attached

Included in this package, as noted, are the resumes of the 2 Site Visitors who completed these on site accreditation visits, as well as copies of the Site Visit report and Plan of Correction completed by the organization. We have also included a set of our Standards of Excellence for core (basic administrative requirements for all community based organizations, and for pharmacy.

We are very confident that the conditions verbally reported by the Board of Pharmacy representative during our appearance at the Licensing Committee of the California State Board of Pharmacy were not present at the time of our visit. Our very experienced pharmacist site visitors would have identified these issues and addressed them. CHAP has over 90 accredited pharmacies nationwide, and accredits more than 5000 locations providing a wide range of community based services. CHAP does receive oversight and validation of our work from CMS as part of our deeming authority for home health and hospice. We have also enclosed in this package the CMS validation report for CHAP for FY 2009, the most recent period available.

Ms. Herald, I hope you will find this information useful in making a determination to continue CHAP's authority to approve sterile compounding pharmacy services in California. I look forward to discussing this in person at our follow-up meeting in February 2011. Meanwhile, if you have any questions or need further information, please give me a call at 202-862-3413.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry A. Duncombe". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry A. Duncombe
President & CEO



COMMUNITY HEALTH ACCREDITATION PROGRAM

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April 22, 2010

Sammy Refua
President/CEO
Pharmaco, Inc. dba Premier Infusion Care
2341 West 205th Street, Unit 113
Torrance, CA 90501

RE: Accreditation for: **Pharmacy**
PTAN: 5136660001

Location and/or Site(s) Accredited:
Pharmaco, Inc. dba Premier
Infusion Care
2341 West 205th Street, Unit
113
Torrance, CA 90501

Site Visit Dates: February 22, 2010 — February 23, 2010
Accreditation Visit Type: Renewal
Accreditation Decision: Accreditation With Required Action
Plan of Correction Accepted Date: March 5, 2010
Accreditation Dates: November 15, 2009 — November 14, 2012

Dear Mr. Refua:

I am pleased to inform you that based on the findings of the site visit conducted at the location and sites(s) referenced above, your organization is in compliance with CHAP Standards of Excellence. The Accepted Plan of Correction is enclosed and details specific required actions cited during the course of the site visit or amended by the Board of Review. The CHAP Board of Review has granted Accreditation to your organization for the term of three (3) years.

The site visit findings determined that your agency is in compliance with CHAP Standards of Excellence and meets the DMEPOS accreditation requirements under Section 1834(A) (20) of the Social Security Act, and the Code of Federal Regulations, Title 42, Part 424.58. Your agency has been approved for the following product categories: DM05, DM12, DM13, PE01, PE02, S01.

Please note that CHAP may conduct surveys less than every three years depending upon CMS regulations and/or the level of deficiencies.

As a CHAP accredited agency, you are required to provide our toll free CHAP Hotline telephone number to all of your clients. This hotline receives consumer complaints and questions about CHAP accredited organizations 24 hours a day, seven days a week. **The CHAP Hotline is 1-800-656-9656.**

Thank you for choosing CHAP as your national accrediting organization! Please contact me at 202-862-3413 if you have any questions.

Sincerely,



Cathy T. Gill
Customer Relations Representative

Enclosure: Accepted Plan of Correction
Certificate of Accreditation
CMS DMEPOS Product Code Key



Community Health Accreditation Program Agency Plan of Correction Response Electronic Toolset

Agency:

Pharmaco, Inc. dba Premier Infusion Care
Torrance, CA

Site:

Pharmaco, Inc. dba Premier Infusion Care
2341 West 205th Street, Unit 113
Torrance, CA 90501

Contact:

John K. Rice, RPh
jrice@premierinfusion.com

Site Visit: 2/22/2010 - 2/23/2010

CCN: 5136660001

Citation:

CHAP STD: CIII.2b
CMS Tag:
CMS CFR:

(CR DIII.2a) It is required that 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.

Evidence:

This requirement was not met as evidenced by 2 of 2 contracts reviewed did not include the following elements of the standard: 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

Agency Response: What action will we take to correct the deficiency cited?

We are currently revising our contracts to include the following elements: 1. Contractor requirements to follow Premier Infusion Care Policies and Procedures. 2. Contractor will be accredited by an approved accreditation program (i.e. C.H.A.P., the Joint Commission or A.C.H.C). In the event the company is not accredited documentation of education, training, qualifications and identification of personnel designated to provide care, services and products will be required. 3. The revised contract will include requirements for participation in Performance Improvement activities to include updates on care provided and patient outcomes. 4. The revised contract will require timely submission of completed nursing notes and/or proof of service and delivery prior to payment for services.

Who is responsible to implement the corrective action?

Sammy Refua is responsible for implementing this corrective action plan.

When will the corrective action be implemented?

The corrective action is currently being implemented and should be complete within 30 days.

What is the monitoring process we will put into place to ensure implementation and effectiveness of the corrective action plan?

All old contracts will be updated with the new contracts and any new contracts will be executed with the new contract. The submission of notes and proof of service will be monitored and no payment for services rendered will be issued until submitted. Furthermore, the Performance Improvement committee will be responsible for the contractors' participation in Performance Improvement activities as needed.



COMMUNITY HEALTH ACCREDITATION PROGRAM

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May 28, 2010

Robert Kelley
President
Atwell Home Care, Inc. dba Apex Infusion Pharmacy
3299 East Hill Street
Signal Hill, CA 90755

RE: Accreditation for: **Pharmacy**
PTAN: 5732120001

Location and/or Site(s) Accredited:
Atwell Home Care, Inc.
3299 East Hill Street
Signal Hill, CA 90755

Site Visit Dates:	March 25, 2010 — March 26, 2010
Accreditation Visit Type:	Renewal
Accreditation Decision:	Accreditation With Required Action
Plan of Correction Accepted Date:	April 15, 2010
Accreditation Dates:	October 18, 2009 — October 17, 2012

Dear Mr. Kelley:

I am pleased to inform you that based on the findings of the site visit conducted at the location and site referenced above, your organization is in compliance with CHAP Standards of Excellence. The Accepted Plan of Correction is enclosed and details specific required actions cited during the course of the site visit or amended by the Board of Review. The CHAP Board of Review has granted Accreditation to your organization for the term of three (3) years.

The site visit findings determined that your agency is in compliance with CHAP Standards of Excellence and meets the DMEPOS accreditation requirements under Section 1834(A) (20) of the Social Security Act, and the Code of Federal Regulations, Title 42, Part 424.58. Your agency has been approved for the following product categories: DM12, PE01, PE02, SO1.

Please note that CHAP may conduct surveys less than every three years depending upon CMS regulations and/or the level of deficiencies.

As a CHAP accredited agency, you are required to provide our toll free CHAP Hotline telephone number to all of your clients. This hotline receives consumer complaints and questions about CHAP accredited organizations 24 hours a day, seven days a week. **The CHAP Hotline is 1-800-656-9656.**

Thank you for choosing CHAP as your national accrediting organization! Please contact me at 202-862-3413 if you have any questions.

Sincerely,



Rebecca Schumann
Customer Relations Representative

CMS DMEPOS Product Code Key

Enclosure: Accepted Plan of Correction
Certificate of Accreditation



Community Health Accreditation Program Agency Plan of Correction Response Electronic Toolset

Agency:

Atwell Home Care, Inc.
Signal Hill, CA

Site:

Atwell Home Care, Inc.
3299 East Hill Street
Signal Hill, CA 90755

Contact:

Robert Kelley - President
bkelley@apex-iv.com

Site Visit: 3/25/2010 - 3/26/2010

CCN: 5732120001

Citation:

CHAP STD: CII.1b
CMS Tag:
CMS CFR:

It is required that the patients' bill of rights include the telephone number for the CHAP hot line, including the hours of operation and the purpose of the hot line to receive complaints or questions about the organization.

Evidence:

This requirement was not met as evidenced by the review of the current bill of rights which does not include the required CHAP information.

Agency Response: What action will we take to correct the deficiency cited?

The CHAP hotline (1-800-656-9656/HOURS:Monday-Friday 9:00a.m.-5:00 p.m.,est) has been added the Admit package for new patients(on the Bill of Rights). This updated Admit package is in place. For ongoing patients, a revised Bill of Rights to be distributed, in place as of 4/8/2010.

Who is responsible to implement the corrective action?

1.Administrative assistant made the changes to the Patient's Bill of Rights document and saved those changes on the computer network. Administrative assistance generates the new patient printouts for the package. Individual Bill of Rights ,updated, are generated for ongoing patients to be included with follow up deliveries. 2.Staff Pharmacist reviewed the revised Bill of Rights for completeness and accuracy. 3.Administrative assistant,Pharmacy Technician and driver(s) will insert revised Bill of Rights into new patient packets. 4.Administrative Assistant,Pharmacy Technician and drivers will include revised Bill of Rights with refill deliveries. 5.Pharmacy staff drivers will deliver revised Bill of Rights with all new(in the revised patient admit package) and refills with the refill delivery ticket.

When will the corrective action be implemented?

1.By 4/8/2010 2.Revised Bill of Rights completed on 4/2/2010. Copies will be completed on 4/6/2010. 3.Distribution began on 4/8/2010.

What is the monitoring process we will put into place to ensure implementation and effectiveness of the corrective action plan?

1.Review new patient admit packs to ensure revised/updated CHAP information is included.
2.Refill delivery ticket will include updated Bill of Rights.

Citation:
CHAP STD: CIII.5a
CMS Tag:
CMS CFR:

It is required that the physical facilities provide a defined and secured area for the receipt, storage and cleaning of contaminated equipment, which is returned from the client's home.

Evidence:

This requirement was not met as evidenced by the inspection of the current facility which finds that there is no dedicated space for the receipt, storage and cleaning of contaminated equipment.

Agency Response: What action will we take to correct the deficiency cited?

1. The previously designated area in the warehouse has been recovered for use and a separate area, marked off with 3'x 10' to provide the contaminated materials return area and a 3'x8' is marked for the bio hazard container location. These areas are clearly delineated stiped markings on the floor and signage on the wall. All items returned from the client's home will be received and stored in this area. The cleaning of appropriate equipment will be assigned to an adjacent area with table top. Steri-cycle waste bins will be in the bio hazard area for pick up.

Who is responsible to implement the corrective action?

Pharmacy Staff- preparing and cleaning of determined sites. Director of Pharmacy for Striping and education.

When will the corrective action be implemented?

Clearing and education started during the site visit discussions. Completion and implementation by 4/12/2010.

What is the monitoring process we will put into place to ensure implementation and effectiveness of the corrective action plan?

Pharmacy Staff will visually inspect twice daily for any exceptions. Exceptions will be recertified immediately and occurrence will be noted in incident report binder-separate OSHA log.

Citation:
CHAP STD: DII.5d
CMS Tag:
CMS CFR:

It is required that all pharmaceuticals, including flush solutions, are dispensed according to the prescription of a duly licensed prescriber.

Evidence: This requirement was not met as evidenced by the review of client records which found that there were valid prescriptions for the IV infusions being dispensed; however, none of the prescriptions included an order for the flush solutions.

Agency Response: What action will we take to correct the deficiency cited?

Pharmacists will include Normal Saline and Heparin Flush orders on all required prescriptions in the CPR+ format, print the document and sign the order as RBTO. Pharmacy Technician and staff will fax the form with signature and return request to prescriber. The faxed document and the returned signed document will be filed in patient's chart. This process will hold for all prescription items necessary to deliver therapy for the end user patient, re: Lidocaine 1% for Rocephin IM administration.

Who is responsible to implement the corrective action?

Pharmacists will create, print and sign the prescription form that includes Saline, Heparin Flush and Lidocaine 1% that requires these therapies. Pharmacy Staff will fax and file the created prescription as well as to file the returned signed prescription.

When will the corrective action be implemented?

This process started during the site visit discussions and was fully implemented on 4/1/2010.

What is the monitoring process we will put into place to ensure implementation and effectiveness of the corrective action plan?

This will be included with the chart audit Q.A. process to ensure flush solutions on orders requiring flush therapy and Lidocaine for I.M. injections, re: with Rocephin.

CURRICULUM VITAE

David Martin, Pharm.D., FACN, CNS

Gadsden Regional Medical Center
1007 Goodyear Avenue
Gadsden, AL 35903

Office (256) 494-4052
Mobile (256) 393-9555
Fax (256) 494-4015

drdavidmartin@yahoo.com

2001 – Present

Assistant Director, Department of Pharmacy & Clinical Manager, Gadsden Regional Medical Center – Pharmacokinetic and ID Service; Metabolic Support Consult Service, Physician Education and Drug Information. AL Licensed Preceptor for Auburn, Samford and South Universities. Committees – Nutrition, Ethics, Transition Team, Infection control, Tumor Board. Resource Management, Closed Chart, CV Team/HCQIP, Antibiotic support team, Diabetes committee.

Appointments: Assistant Profession, Auburn University and Clinical Preceptor, Samford University and South University.

Research/Projects:

- DVT Free Study and Research Grant
- HIT antibody surveillance Research Grant
- Clostridium Difficile Study
- Adverse Drug Reactions
- Parenteral Nutrition audit
- MRSA Sensitivity comparison linezolid v Vancomycin research grant
- LMWH bridging -- Heparin to Coumadin at home

- Automation of once-a-day-all-in-one peripheral and central parenteral nutrition
- Implemented advanced lipid testing (ALT) in collaboration with clinical laboratory
- Coordinator for Transition Team -- care coordination for complex patients
- Member HCFA Alabama Health Care Quality Improvement Program (HCQIP)
- InterQual

1991 - 2001

Consulting Practice – pharmaceutical, medical & alternative medicine, business management, marketing, revenue enhancement, new business development, clinical research, health awareness, patient and medical education.

Consulting Projects

Lifeline Medical, CEO, Mexico, Mexico City

Genesis Center, Inc.: Developed and established a medical nutrition and health awareness practice specializing in coronary artery disease, cancer and nutrition related diseases.

Alpha Research, Inc.: Established and coordinate FDA Clinical trials in cancer. Treatment with Alpha Peptide – clinical phase I and pharmacokinetic studies.

Global Cancer Research Foundation: Coordinate animal trials with topical product for malignant melanoma.

Medicasa de Guadalajara SA de CV: Establish a high tech home care, infusion pharmacy and nursing service in Mexico City. Conduct Clinical trials in conventional and alternative medicine for US companies in Mexico.

Mexicare SA de CV: Developed and implemented a high tech home care company in Mexico City providing IV

services, nursing and respiratory care. Provided consulting for management, marketing and clinical services.

Americare, Inc.: Established a medical case management company for medical clinics for home care services. Developed patient benefit verification, electronic billing, collection and clinical protocols.

Rockdale Medical Center: Established Metabolic Support Service. Provided hospital medical staff with consulting service.

Shallowford Hospital: Established Metabolic Support Service. Provided hospital medical staff with consulting service.

Humana Hospital: Established Metabolic Support Service. Provided hospital medical staff with consulting service.

Previous - HOSPITAL CONSULTING PRIVILEGES

Georgia Baptist Medical Center, Director, Metabolic Support (12 years)
Grady Memorial Hospital, Atlanta (4 years)
Shallowford Medical Center, Atlanta (5 years)
Humana Medical Center, Snellville, GA (13 years)
Rockdale County Regional Medical Center, Conyers, GA (4 years)

US MILITARY Viet Nam Veteran, Corpsman US Navy
Air Commander, USCG Auxiliary

TEACHING EXPERIENCE

1978 to 1986 Associate Professor (tenured) and Director, Postgraduate Residency Program. Mercer University, School of Pharmacy. Primary Graduate courses: Parenteral-Enteral Nutrition 555; Advanced Metabolic Support 556; Design, Implementation and Administration of a Nutritional Support Services 557; Clinical Research Seminar in Applied Metabolic

Support 558. Established residency training program. Responsible for contracting, placing, and evaluating residents and research fellow.

CONCURRENT APPOINTMENTS

Director, Metabolic Support Service, Georgia Baptist Medical Center. Design, implemented and administered formal nutritional support services.

Clinical Associate in Nutrition & Dental Health, Emory University, School of Dentistry. Provided lectures and clinical rotations for Dental students.

Clinical Assistant Professor, Emory University, School of Medicine, Department of Community Health (Masters Program). Professor -- Clinical Nutrition and provided clinical training for graduate student in nutrition.

Pharmacy – Clinical, Teaching and Management Experience Prior 1991

1988 to 1991 **Regional Manager**, Syncor International Corporation. Responsible for opening and diversifying home care centers including operations and sales. Chair, Quality Assurance Committee with responsibility for coordinating Company-wide Drug Information and Pharmacokinetic Services. Instructor for Professional staff training of nurses, pharmacists, & sales representatives. Manage 7.2 million dollar budget with continuous improvement in decreasing cost of materials, operating labor, DSO, bad debt, and increasing inventory turns and profit contribution. Received Outstanding Achievement Award in January 1989. In addition to Regional Responsibilities in August 1990 became Manager for Syncor Management Services, Inc. for Physician Partnerships. This includes DME/02, PT, infusion therapy and Nursing.

Significant contribution:

-Implemented physician/hospital/ nursing home limited partnership (3 operation, 17 in development)

-Designed and implemented quality assurance committee for JCAHO and outcome monitoring

- Opened with Atlanta, Jacksonville, and Orlando pharmacies with Atlanta achieving over a million in sales the first year
- Development and implemented a purchasing committee
- Implemented the first regional training meeting
- Implemented the first national sales meeting
- Consolidated monthly reporting system
- Designed and implemented the drug information services and pharmacokinetic services
- Initiated the development of electronic charting and electronic news letter
- Designed and implemented the postgraduate residency training program
- Implemented Gamimune for EB syndrome and tocolytic therapy Program
- Designed and implemented use of sales software for accounts follow-up and reporting.

1986 to 1988 National Operations Director, Pharmacy Services of America, Charter Medical. Responsible for start-up, P & L, AR's, clinical, and administrative activities. This includes purchasing, implementing innovative revenue programs, and coordinating pharmacy service with DME, Respiratory and Nursing Divisions. Opened three pharmacies the first year. responsible for sales, operations, and contracts.

(1978 to 1986) **Mercer University, School of Pharmacy**, Associate Professor. (see teaching experience)

1973 to 1975 **Director, Clinical Pharmacy**, Mercy Center Hospital. Parenteral Nutrition Specialist. Responsible for: Drug information, IV admixture, cardio-pulmonary resuscitation team, editor of pharmacy newsletter, Instructor for pharmacy externs (University of Illinois), inservice education, patient education/counseling and provided pharmacology lectured to Waubensee College, School of Nursing.

1972 - 1973 **Staff pharmacist**, Loyola University Hospital. Experience in drug information, IV admixture, unit dose and computerized patient profile.

1971 - 1972 **Staff pharmacist**, Hines VA Hospital. Responsibilities -- Monitor patients on TPN, acting inpatient Section Chief, career counselor. Research projects: lung lavage, metabolic studies, and cadaver kidney perfusion.

1970 - 1971 **Sales Representative**, Eli Lilly Pharmaceutical Company. Urban territory, calling on physicians, hospitals and dentists. Held hospital and convention displays.

1968 - 1970 **Assistant Manager**, Miami Plaza Drugs. Responsible for payroll, purchasing, merchandising and clerks.

1966 - 1968 **Corpsman**, Medical Department US Navy aboard heavy guide missile cruiser in Vietnam. Assigned as pharmacist. Responsible for drug dispensing, sick call, laboratory, medical records and direct patient care.

COMMUNITY SERVICE/ADVISORY EXPERIENCE

Peer Review Editor, Journal of Hospital Formulary.

Consultant, Professional Reimbursement, PEN-Medicare Division, Blue Cross/Blue Shield. Provide validation studies, product categorization, and inservice education.

Home Health Care Consultant, Pharmacy Task Force of Georgia. Review and update State Pharmacy Laws.

Editorial Board, International Nutrition. Review international clinical research papers for publication.

Appointed to United States Pharmacopeia Nutrition Review and Advisory member. Review and research official compendium and product pharmacotherapeutics.

Pharmacy Advisory Board, LyphoMed, Inc. Review new product for packaging price and clinical application.

Medical Advisory Board, Visiting Nurses Association, Metropolitan Atlanta Division. Review and approve clinical protocols & QA for blood transfusions.

Editorial Advisory Board, Nutritional Support Services Journal. Review Articles for publication.

National Advisory Board, Data Med, Inc. Provided beta-site clinical evaluation of clinical software for nutritional support and pharmacokinetics.

Education Consultant, Healthdyne Corporation. Responsible for development of clinical projects and strategic planning.

Medical Advisory Board, Navaco Laboratories.

EDUCATION

- | | |
|-------------|--|
| 1977 - 1978 | Post-doctoral Residency in Metabolic Support , Grady Memorial Hospital. Twelve-month clinical training in patient care and research. Provided consultative service to medical staff. Established the Metabolic Support Service. |
| 1975 - 1977 | Doctor of Pharmacy , Mercer University. Emphasis was in clinical pharmacology, pharmacokinetics, pathophysiology, clinical chemistry, radioisotopes, statistics and research design. |
| 1962 - 1966 | BSc. in Pharmacy , University of Illinois. |
| 1961 - 1962 | Pre-Pharmacy , Wright College |

CERTIFICATION/LICENSURE

Fellow, American College of Nutrition (FACN)

Certified Nutrition Specialist (CNS)

Registered Pharmacist: State of Georgia # 011749
State of Illinois # 051-027119
State of Alabama # 14309

Licensed Pharmacy Preceptor (AL): expires 2/28/06

Certification for Laboratory Test, FL State Board PSL99001

FDA, HAACP Certified Quality Seafood Inspector - food borne illness

BLS – valid until 8/2007

SPECIALIZED TRAINING

National Library of Medicine (Medlars - Searcher) Trained at NLM, Bethesda. Medline, Toxline, Cancerlit, PDQ

Sales Training, Eli Lilly. 5-week Course, Indianapolis.

PSS-III (Xerox sales and sales manager course), Chatsworth, CA. Phase I and II. Need-Satisfaction selling and coaching.

Reimbursement Computer Program Training, Chatsworth, CA

"Leadership for Supervisors", AMA Course, Washington, DC

PROFESSIONAL HIGHLIGHTS

USP Nutrition Expert Panel (1985 - 1990 US Pharmacopeia)

Former President, American Society of Nutritional Support Services

Former President, Atlanta Academy of Institutional Pharmacy

RESEARCH GRANTS (Highlights)

Principal Investigator: "HEP-4 Comparison to Traditional Ab Testing", GSK

Principal Investigator: "DVT Free Multi-Center Study", Aventis

Educational Grant: "Daptomycin in MRSA – a sensitivity evaluation",
Cubicin

Principal Investigator: "Linezolid E-strip testing v. Vancomycin",
Pharmacia

Educational Grant: "Enoxaparin Bridging Heparin to Coumadin", Pharmacia

Principal Investigator: "Antimicrobial Tube Feeding", EDIC Medical

Principal Investigator: "Treatment of Intractable Diarrhea in AIDS Patients
with Amylyte, EDIC Medical

Principal Investigator: "Elemental Protein Module", Ross Laboratories

Principal Investigator: "B12 and Folic Acid Status in Preterm Neonates",
US Vitamin Corporation

Principal Investigator: "B12 and Folic Acid Stability in Parenteral
Nutrition", US Vitamin Corporation

Co-Investigator: "Serum and Urine Levels of Vitamins in Patients
Receiving Parenteral Nutrition", US Vitamin Corporation

Investigator: "Metabolic Evaluation of 20% Intravenous Fat Emulsion for
Hemolysis", Cutter Laboratories

Investigator: "MVI-12 in Parenteral Nutrition", US Vitamin Corporation

Investigator: "Glucosyn in Peripheral Parenteral Nutrition, Abbott
Laboratories

Investigator: "Fat-Amino Acid-Dextrose -- All-in One Infusion", Phase III Clinical Trials, Cutter Laboratories

Investigator: "BCAA in Modular Tube Feeding", Navaho Laboratories

Investigator: "3-Methylhistidine Turnover in Critically Ill Patients", Mercer University

Investigator: "Hypouricemia with Parenteral Nutrition", Mercer University

Principal Investigator: "Cost Impact of Computer Assisted Neonatal Nutrition", ASHP, 7-center Research Foundation

PATENT

HMO Tube for enteral nutrition, US Patent Office, 6/83 # 4,390,017

PUBLICATIONS 39 Publications – available upon request

PROFESSIONAL PRESENTATIONS (examples 2005)

2005

12/8 "Heparin-PLT-4 Point of Care Testing" (accepted for poster presentation) ASHP Clinical Midyear Meeting, Las Vegas.

9/7 "Medication Safety for Nurses", GRMC, Nursing Staff.

9/2 "Update – Critical Care Medication", GRMC, Critical Care Nurse.

6/12 "Heparin-Induced Thrombocytopenia" Alabama Society of Health System Pharmacists", Destin, AL.

Note: Comprehensive list of Presentations and/or References Available upon request.

55 Falls Landing Road
Deep River, Connecticut 06417

Telephone 860-227-0453
Fax 860-526-7836
E-mail RICK61@prodigy.net

Richard R. Daniels, Jr.

Objective

To utilize my interest in clinical pharmacy, in a setting which allows for interaction with patients and other healthcare professionals. To utilize my communication and educational skills in a way that improves the delivery of pharmaceutical care.

Experience

2005 - present PharMerica Corporation South Windsor, CT
(formerly Kindred Pharmacy Services)

Consultant Pharmacist

- Monthly drug regimen reviews and nursing station inspections.
- Quarterly Medical Staff meetings.
- In-service education of facility staff.
- Clinical Coordinator
- Drug Handbook Revision Committee

2001 - 2005 NeighborCare Windsor, CT

Consultant Pharmacist

- Monthly drug regimen reviews and nursing station inspections.
- Quarterly Medical Staff meetings.
- In-service education of facility staff.

2002 - present Community Health Accreditation New York, NY
Pharmacy Surveyor Program (CHAP)

- On-site survey of pharmacies (home infusion and respiratory compounding) for accreditation by CHAP.
- Review and revision of pharmacy standards, including the standards of USP 797.

2000 - present CVS Pharmacy Woonsocket, RI
Part-time Pharmacist

1991 - present Town of Deep River Deep River, CT
Selectman

- Budgeting, personnel management, contract negotiation and fiscal management.
- Educational programs for compliance with OSHA Bloodborne Pathogen regulations.

1991 - present Deep River Visiting Nurses Deep River, CT
Board of Directors

- President since 1991.
- Development of policy to maintain licensure and accreditation.
- Strategic planning and marketing.
- Fiscal management and budgeting.

- Public health promotion.

1980 - present State of Connecticut Hartford, CT
Emergency Medical Technician - Office of Emergency Medical Services

- Deep River Ambulance Association - volunteer

2000 - 2002 American Pharmaceutical Services New London, CT
Staff Pharmacist / Pharmacy Consultant

- Retail and Long-term care pharmacy.
- Unit-dose, IV, TPN, and PCA.
- Personnel management.
- Pharmacy consultant services.

1998 - 2000 CVS Pharmacy Hartford, CT
Pharmacy Manager / Team Leader

- Maintenance of customer service standards.
- Inventory and cost management.
- Personnel management.

1997 - 1998 CVS Pharmacy Woonsocket, RI
Pharmacy Scheduler / Floater Pharmacist

- Scheduling and pharmacist's duties for 48 stores in Connecticut

1988 - 1997 CVS Pharmacy West Hartford, CT
Staff Pharmacist

1988 Madison Plaza Pharmacy Madison, CT
Staff Pharmacist

1984 - 1988 Old Lyme Pharmacy Old Lyme, CT
Staff Pharmacist

1983 - 1995 State of Connecticut Hartford, CT
Emergency Medical Services Instructor – Office of Emergency Medical Services

- Instruction in accordance with standards of the United States Department of Transportation for certification / re-certification as an Emergency Medical Technician or Medical Response Technician.

Education

1995 - 2005 Creighton University Omaha, NE

- Doctor of Pharmacy

1979 - 1983 University of Connecticut Storrs, CT

- B.Sc. Pharmacy

Affiliations

American Society of Consultant Pharmacists

**Licensure /
Certification**

State of Connecticut - 1984

State of Florida - 1997

Commonwealth of Massachusetts - 1997

Certified Geriatric Pharmacist - 2002

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.

EVALUATION SUMMARY		
<i>Please transfer your ratings to the left side and then choose the overall ratings on the right side by checking the appropriate box.</i>		
EVALUATION COMPONENTS		OVERALL EVALUATION
Customer Satisfaction	Select Rating	Select Rating
Job Acumen	Select Rating	
Results	Select Rating	
Team Success	Select Rating	
Professional Development	Select Rating	
Competencies	Select Rating	
Goal Accomplishment	Select Rating	
SIGNATURES		
<i>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.</i>		
Employee: (all reviews)		Date:
Supervisor: (all reviews)		Date:
Chief Operating Officer: (annual review only)		Date:
Human Resources: (annual review only)		Date:
EMPLOYEE COMMENTS (optional)		

*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!*

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

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

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

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

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

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

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

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

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

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

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

Attachment 2

Excerpt: Minutes of the October 2010 Licensing Committee Meeting

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

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

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

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

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

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

Public Comment:

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

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

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

There was no additional committee discussion or public comment.

--END OF OCTOBER 2010 LICENSING COMMITTEE MINUTES EXCERPT--

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

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.

Authority cited: section 4005, Business and Professions Code. Reference: section 4232, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

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.

Authority cited: Section 4005 Business and Professions Code. Reference: Section 4232, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code.

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Attachment 3

Hospital Repopulation after Evacuation Guidelines and Checklist

Purpose

The purpose of this document is to identify hospital operational and safety best practices, as well as regulatory agency requirements, which must be considered when repopulating after full or partial evacuation of general acute care hospital inpatient building(s) (GACHB). The association sought consultation from the following agencies prior to publishing this document: State of California Office of Statewide Health Planning and Development (OSHPD), California Department of Public Health (CDPH) Licensing and Certification (L&C) and State Board of Pharmacy (BOP). These guidelines do not supersede existing state statutes or regulations. In the event of a direct conflict with existing statutes and/or regulations, facilities should follow applicable statutes and/or regulations.

Overview

An evacuation of a GACHB occurs following an incident or series of incidents that result in a situation which is, or may become, detrimental to the well-being of patients, staff, workers or visitors in the hospital. Any evacuation of a hospital building should be implemented in accordance with the facility's Emergency Operations Plan (EOP), as well as in coordination with Operational Area Disaster and Emergency Management Plan(s).

Evacuations can consist of the following scenarios:

- Full evacuation of the hospital campus
- Full evacuation of one or more inpatient care buildings on campus
- Partial evacuation of one or more inpatient care buildings

Buildings that house inpatients who are released or transferred to make room to receive inpatients evacuated from other inpatient care buildings are not considered buildings that experienced an evacuation. However, program flexibility may be required from the L&C district office to treat patients in these buildings.

An evacuation can be voluntary or mandatory. A voluntary evacuation decision is made by the Chief Executive Officer (CEO) or Incident Commander (IC) and is based on the hospital's EOP and available internal and external information. A mandatory evacuation is an evacuation that is ordered by an authorized governmental authority having jurisdiction. Government authorities with jurisdiction include, but are not limited to, fire, law enforcement, OSHPD and local emergency services.

A hospital may be able to remain operational and/or avoid voluntary evacuation by seeking program flexibility from the appropriate L&C district office. For example, for a partial evacuation, the hospital may be able to move inpatients from damaged units by expanding capacity in operational inpatient units or maintain limited operations by the use of alternate treatment areas while preparing evacuated areas for repopulation.

Recovery and repopulation of evacuated facilities should be included in hospital preparedness activities and its EOP. [*Reference CHA Hospital Evacuation and Shelter in Place Checklists*] Steps taken prior to, or at the time of evacuation, will facilitate more efficient repopulation of facilities, for example:

- Report partial or full evacuation to L&C district office, Operational Area Office of Emergency Services (OES) and the Local Emergency Medical Services Agency (LEMSA) and other agencies, as appropriate ¹
- Maintain surveillance monitoring of temperatures, refrigeration, air/water quality, pharmaceuticals and facility security, as feasible

The hospital CEO, his/her designee, or the IC has the ultimate responsibility to ensure a safe environment for patients, staff and visitors. In making a decision to evacuate or repopulate, the CEO or IC should use the Hospital Incident Command System (HICS) and, in doing so give consideration to consulting with key departments, the chief of the medical staff, the L&C district office, LEMSA, the local department of health, and other public safety and utility agencies, as appropriate.

Also, the CEO or IC will:

- A. Give consideration to whether an evacuation may be more harmful to the patients, staff and visitors than sheltering in place (*Refer to the CHA Evacuation Plan and Shelter in Place Checklists*).
- B. Consult with appropriate hospital departments and external agencies in making a determination regarding whether the facility has adequate resources and is clean, sanitary and safe to repopulate and/or receive patients after an evacuation. Each decision shall be considered on a case-by-case basis. It is understood that an evacuated hospital/building will not be staffed, nor will perishable resources be re-stocked until necessary approvals are received and repopulation plans are initiated.
- C. Base the decision of whether to repopulate on the merits of the evacuated area alone and not be biased by the argument that returning to the evacuated area is better than where patients are currently located. Whether patients need to move from their current temporary location is a separate issue. An alternate temporary location may be more appropriate than repopulating them in an evacuated building.

¹ **Reportable Unusual Occurrences**

Title 22 requires general acute care hospitals and acute psychiatric hospitals to report any occurrence such as an epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence which threatens the welfare, safety, or health of patients, personnel, or visitors, as soon as reasonably practicable, by telephone or telegraph, to the local health officer and to the California Department of Public Health (CDPH). The hospital must furnish other pertinent information related to the occurrence as may be requested by the local health officer or CDPH [Title 22, California Code of Regulations, Sections 70737 (general acute care hospital) and 71535 (acute psychiatric hospital)].

Exactly which types of incidents constitute an “unusual occurrence” has not been clarified by CDPH. CDPH is aware that its employees as well as hospital employees have inconsistent interpretations of this requirement.

- D. Be aware that any evacuation is considered a reportable event to L&C. Therefore, L&C may visit the facility as part of the reportable event process. A reportable event visit and repopulation visit are separate visits; however, it is possible that both could be done at the same time depending on the nature of the evacuation. The CEO/IC may call L&C at any time to request a repopulation approval visit. However, this should be done only upon the CEO's assessment and confirmation that the facility is ready for repopulation. This is to ensure that L&C and, if needed, OSHPD and fire marshal staff will not have to make multiple visits to facilities during a disaster event.

Section 130025 (a) of the Health and Safety Code states, "In the event of a seismic event, or other natural or manmade calamity that the office (OSHPD) believes is of a magnitude so that it may have compromised the structural integrity of a hospital building, or any major system of a hospital building, the office shall send one or more authorized representatives to examine the structure or system. "System" for these purposes shall include, but not be limited to, the electrical, mechanical, plumbing, and fire and life safety system of the hospital building. If, in the opinion of the office, the structural integrity of the hospital building or any system has been compromised and damaged to a degree that the hospital building has been made unsafe to occupy, the office may cause to be placed on the hospital building either a red tag, a yellow tag, or a green tag."

A hospital building with a red tag (unsafe) or a yellow tag (restricted access) cannot be repopulated until the tag is removed. A green tag indicates that the building is safe for repopulation.

Hospital Repopulation after Evacuation Checklists

Hierarchy of Repopulation Approval(s)

Dependent upon circumstances, the following sequential steps should be expected prior to the repopulation of evacuated hospital facilities.

	Date Completed
A. Local government agencies have removed restrictions, if any, related to the environmental quality in the area or facility for the types of patients to be moved back into the facility.	
B. Local Fire Department and/or Law Enforcement agency representative allows re-entry to the specific evacuated neighborhood in which hospital is located and/or allows re-entry to evacuated facilities, as applicable.	
C. If structural integrity or any major building system is compromised, OSHPD inspects and repopulation cannot occur until any red and yellow building tags are removed from the impacted building by OSHPD.	
D. If required, due to prolonged loss of power and refrigeration or breach of pharmaceutical security, State Pharmacy Board may conduct a site visit to approve measures taken to restore Pharmacy capacity and safety.	
E. The CEO/IC oversees an assessment of environmental safety, facilities, operations and resources, including the factors identified in the General All Hazards Repopulation Factors checklist below, and prepare the facility for repopulation.	
F. The CEO/IC maintains communication with the L&C District Office regarding facility status, progress and estimated timeframes for reopening of facility (ies). Depending upon the circumstances, L&C may schedule a reportable event visit.	
G. Once the CEO/IC makes a determination, based on best judgment, that the facility is ready to repopulate, L&C is notified and: <ol style="list-style-type: none"> 1) If necessary, an L&C repopulation inspection is scheduled, or, 2) Repopulation is initiated. 	
H. If an L&C repopulation visit is required: <ol style="list-style-type: none"> 1) If necessary, additional actions or agency reviews may be requested by L&C; and/or, 2) The determination is made that hospital facilities are safe for patients, staff and visitors, programs and services can be resumed, and repopulation can be initiated. 	

General All-Hazards Hospital Re-Population Factors – Steps

The following factors – steps should be considered as appropriate to the type of evacuation

	Status/Date
A. Facilities are determined to be structurally sound and safe, and systems are not compromised, for occupancy. If not safe, may require repairs/retrofits/replacements that need to be approved by OSHPD, fire marshal and L&C.	
B. Air particulate exposure levels (e.g., smoke, chemicals) in buildings are documented to be reduced to acceptable/safe levels as defined by Cal/OSHA permissible exposure limits (PELS) and local Air Quality Management District Standards using available methods (e.g., air scrubbers, open windows, blowers, HAZWOPER response, etc), if needed. Only test equipment appropriate to the hazard should be used to determine safe levels of habitability and may require an outside testing laboratory service.	
C. Hospital shall have a plan to prepare for and implement repopulation.	
D. All interior and exterior surfaces/areas are clean and free of debris (e.g., counters, walls, drawers, closets, roof, parking facilities, etc).	
E. All filters in the facility, HVAC systems, and generators, etc. should be cleaned/replaced, if needed.	
F. Replace or clean linens, drapes, and upholstery, if needed.	
G. All items within the facility that can be affected by spoilage due to loss of power and/or high temperatures are tested and repaired/replaced/quarantined, as needed (e.g., food, medications, radioactive supplies and equipment, computerized diagnostics, etc.).	
H. Essential functions and supplies/supply chains (pharmacy, supplies, laundry, etc.) are returned to operational status. The facility's ability to provide essential services should be sustainable for the long term. Program Flex may be an option subject to L&C District Office approval (e.g., contracted food or pharmacy services).	
I. Vandalism and/or looting damage, if applicable, is repaired and alleviated.	
J. Full and non-abbreviated generator and smoke detector tests are completed, if needed.	
K. HVAC systems are tested and operational, if needed.	
L. Utilities are tested and operational (electricity, water supply and quality, plumbing, etc.).	
M. Dietary Services are operational and sustainable for the long term; in the case of damage to kitchens/equipment, program flex approval from L&C may be requested for contract services during repairs.	
N. Determine if the laboratory evacuation plan was followed. If the laboratory evacuation plan was not adhered to, or found to have limitations, a mitigation response is necessary.	

October 27, 2010

TO: Hospital Emergency Preparedness Contacts

FROM: [HPP Coordinator]

SUBJECT: *Hospital Repopulation after Evacuation Guidelines and Checklist*

Attached is a new tool for hospitals entitled *Hospital Repopulation after Evacuation Guidelines and Checklist (Repopulation Guidelines)*. The purpose of the document is to identify hospital operational and safety best practices, as well as regulatory agency requirements, which must be considered when repopulating after full or partial evacuation of general acute care hospital inpatient building(s) (GACHB). The association sought consultation from a number of State agencies prior to publishing this document.

The initiative to develop *Repopulation Guidelines* was undertaken to identify factors and steps that will allow an evacuated hospital to return to normal operations as quickly as possible. While events and circumstances may vary, efforts focused on identification of State agency requirements and the basic steps that must be considered to meet those requirements.

Also attached is a revised *CHA Hospital Evacuation Plan Checklist* incorporating updates and references to the *Repopulation Guidelines* in the section for Recovery, Reopening and Repopulation after Evacuation.

The *Repopulation Guidelines* should be used to review and update hospital Evacuation and Shelter in Place plans, as necessary, to ensure that they are consistent and to allow the hospital to consider repopulation requirements prior to evacuation.

These tools and documents will also be available on CHA's HPP website at www.calhospitalprepare.org. Should you have any questions please feel free to contact me, or you may contact Cheri Hummel, our program director at chummel@calhospital.org.

Hospital Evacuation Plan (Checklist)

PURPOSE - OVERVIEW:

To provide guidance in the development or update of a hospital evacuation plan containing detailed information, instructions, and procedures that can be engaged in any emergency situation necessitating either full or partial hospital evacuation, as well as sheltering in place.

The expectation will be that staff may need to accompany patients and work in staging areas, in local government Alternative Care Sites (ACS) and/or at receiving facilities, subject to receiving proper emergency credentials. Drills, training and reviews must be conducted to ensure that staff have a working knowledge of the plan and to ensure that the plan is workable.

The plan should be consistent with federal NIMS and The Joint Commission requirements

Template Element	Reference
1. General Plan Requirements	
<ul style="list-style-type: none"> Integrated with other pertinent protocols in facility's comprehensive Emergency Operations Plan (EOP), including activation of hospital incident command system (ICS) 	
<ul style="list-style-type: none"> Identify back-up measures for key infrastructure components/resources as appropriate 	
<ul style="list-style-type: none"> Assigned responsibilities and formal process for review and update of Evacuation Plan (Plan), including incorporation of after action report results 	
<ul style="list-style-type: none"> Staff training including Plan overview, specific roles and responsibilities, utilization of evacuation equipment, techniques for lifting and carrying patients, and knowledge of primary/alternate evacuation routes 	
<ul style="list-style-type: none"> Uses standard terminology in common and consistent plain English language and emphasizes its use by staff during an evacuation 	
2. Activation	
<ul style="list-style-type: none"> Define criteria and authority for decision to activate the Plan 	
<ul style="list-style-type: none"> Define how the Plan is activated and how it integrates with the hospital incident command system (ICS) and EOP. Define the plan for communication and coordination with the Multi-Agency Coordination (MAC) System and/or the operational area ICS (e.g., EMS, PH DOC or City/County EOC) 	
<ul style="list-style-type: none"> Document how Shelter in Place critical decision making (<i>Exhibit 1</i>) has been integrated into Evacuation Plan including a determination whether State Program Flexibility would allow hospital to avoid full evacuation (e.g., alternate use of facilities) 	
<ul style="list-style-type: none"> Identify and/or reference Public Information Plan (PIO, JIC coordination as appropriate) 	
<ul style="list-style-type: none"> Identify alert and notifications to local (e.g., EMS, PH, Fire) and state agencies (e.g., L&C) regarding potential and/or intent to evacuate facilities and how communication will be maintained during and after evacuation 	
<ul style="list-style-type: none"> Define the type/level of evacuation that could occur (shelter in place, partial horizontal/vertical/ external, full) 	
<ul style="list-style-type: none"> Describe the phases of implementation (i.e. staff notification, accessing available resources and equipment, preparation of patients and essential patient supplies and equipment) 	
<ul style="list-style-type: none"> Define routes and exits identified for evacuation, including area, facility and campus diagrams 	
<ul style="list-style-type: none"> Describe the protocols for accepting and orienting staff and volunteers from other facilities to assist with evacuation 	
<ul style="list-style-type: none"> Describe the plan for the order of removal of patients and planned route of movement (prioritization) as relevant to event and evacuation type 	

Note: this document does not represent a requirement for hospitals to reorganize their plans to coincide with the checklists; it is provided to assist hospitals in assessing and updating their evacuation plans. Rev: October 27, 2010

Template Element	Reference
3. Securing Hospital Site	
<ul style="list-style-type: none"> Define the hospital security access (e.g., lockdown) plan, including ambulance diversion 	
<ul style="list-style-type: none"> Describe the alternate sites identified for media center and labor pool, including nursing and medical staff 	
<ul style="list-style-type: none"> Define the procedures for securing the facility and perimeter 	
<ul style="list-style-type: none"> Describe procedures for security and/or management of controlled substances 	
<ul style="list-style-type: none"> Describe procedures for securing utilities, including shutting down/controlling gas, medical gases, water and electricity as appropriate to event (potentially shutting down or activating generators); consideration should be given to potential impact on equipment and systems and potential for spoilage of food and pharmaceuticals. 	
<ul style="list-style-type: none"> Describe how coordination with local public safety for determination of inner and outer perimeters for hospital and staging area sites will be established 	
4. Identification of the Alternate Site(s) – Receiving Facilities	
<ul style="list-style-type: none"> Identify receiving facilities and government sponsored alternative care sites and contact information 	
<ul style="list-style-type: none"> Identify/reference any written documentation that confirms the commitment of these facilities (Memorandum of Understanding, Contract, Local Emergency Plans, etc.) 	
<ul style="list-style-type: none"> Define process for reaffirming/updating agreements 	
<ul style="list-style-type: none"> Define the process for contacting Operational Area Emergency Medical Services – Departmental Operations Center (DOC) and/or facilities to: <ul style="list-style-type: none"> ascertain availability at the time of the evacuation and assist with transport notify identified facilities that patients will be evacuated to their facilities 	
5. Resources/Evacuation	
<ul style="list-style-type: none"> Identify resources/equipment available to move patients from rooms/floors and the procedure in place for inventory control 	
<ul style="list-style-type: none"> Identify the location of additional resources needed such as additional lighting sources, i.e., flashlights and batteries and portable monitors and ventilators 	
<ul style="list-style-type: none"> Identify a clearly marked storage area available 24/7 for this equipment 	
<ul style="list-style-type: none"> Define the protocol for staff training on equipment use 	
<ul style="list-style-type: none"> Define the protocol to be utilized for on-going assessment of the patient status for equipment and transportation needs in the event of an evacuation 	
<ul style="list-style-type: none"> Describe how communication will be maintained, and documented, for staff and outside resources 	
6. Resources/Continuity of Care	
<p>The Plan must address how continuity of care will be maintained during an evacuation for patients at all levels of clinical complexity and disability including:</p>	
<ul style="list-style-type: none"> How to maintain continuity of care if the usual equipment is not available during the evacuation process 	
<ul style="list-style-type: none"> How equipment identified as necessary to provide continuity of care can be moved with the patient, how you will identify and track patient’s own equipment, and meet requirements for providing power to electrical equipment (e.g., beds, wheelchairs, ventilators, etc) 	
<ul style="list-style-type: none"> What resources are available to maintain isolation precautions for the safety of staff and patients, including communication of need for precautions above Standard Precautions 	
<ul style="list-style-type: none"> How staff will be trained and drilled on the evacuation process/Plan 	
<ul style="list-style-type: none"> Identify how services that may need to continue will be provided or arranged for while repairs to facilities are being made as necessary (e.g., day treatment, dialysis) 	

Note: this document does not represent a requirement for hospitals to reorganize their plans to coincide with the checklists; it is provided to assist hospitals in assessing and updating their evacuation plans. Rev: October 27, 2010

Template Element	Reference
7. External Transportation Resources	
<ul style="list-style-type: none"> Identify pre-designated areas to congregate patients according to predetermined criteria (i.e., event, acuity, mobility levels) 	
<ul style="list-style-type: none"> List and numbers of patients by type and/or transportation resources needed (buses, vans, ALS and BLS ambulances, ambulettes, trucks, wheelchair vans, etc.) 	
<ul style="list-style-type: none"> Describe the process for contacting EMS (e.g., DOC/EOC) to request and to coordinate transportation vehicle needs/resources with patient needs (i.e. patient acuity level, wheelchairs, life support, bariatric) 	
<ul style="list-style-type: none"> Identify hospitals primary and secondary/alternate transportation resources to be available if needed, including contact information 	
<ul style="list-style-type: none"> Reference documentation that confirms the commitment of required transportation resources (e.g., Memorandum of Understanding, Contract, County Emergency Plans or Protocols) 	
<ul style="list-style-type: none"> Define the process for reaffirming and updating agreements and plans 	
8. Patient Evacuation	
<ul style="list-style-type: none"> Specify the protocol to assure that the patient destination is compatible to patient acuity and health care needs, as possible 	
<ul style="list-style-type: none"> Provide evacuees with standardized visual identifiers, such as a color-coded wristband or evacuation tag, to help personnel rapidly identify special needs for high risk conditions that, if not easily identified, could lead to injury or death of an evacuee. 	
<ul style="list-style-type: none"> Establish protocols for sharing special needs information, as appropriate, with personnel participating in the evacuation, including transport agencies, receiving facilities, alternative care sites, shelters and others involved in evacuee patient care. 	
<ul style="list-style-type: none"> Identify the resources necessary to address patient needs during transport, how to access and responsibility for acquiring and sending with the patient (e.g., "go bags", food, water, medications, etc.) 	
<ul style="list-style-type: none"> Document staff training and exercises on the traffic flow and the movement of patients to a staging area 	
9. Tracking Destination/Arrival of Patients	
<ul style="list-style-type: none"> A patient identification wrist band (or equivalent identification) must be intact on all patients 	
<ul style="list-style-type: none"> Describe the process to be utilized to track the arrival of each patient at the destination 	
<ul style="list-style-type: none"> The tracking form* should contain key patient information, including the following: 	
<ul style="list-style-type: none"> o Medical Record Number 	
<ul style="list-style-type: none"> o Time left the facility 	
<ul style="list-style-type: none"> o Name of transporting agency 	
<ul style="list-style-type: none"> o Original chart sent with patient (yes or no) 	
<ul style="list-style-type: none"> o Critical medical record information (orders, medications list, face sheet) (yes or no) 	
<ul style="list-style-type: none"> o Meds sent with patient (List) 	
<ul style="list-style-type: none"> o Equipment sent with patient (list) 	
<ul style="list-style-type: none"> o Family notified of transfer (yes or no) 	
<ul style="list-style-type: none"> o Private MD notified of transfer (yes or no) 	
<p><i>*Note: Example HICS tracking forms are available</i></p>	
<ul style="list-style-type: none"> Identify protocol for linking and reuniting patients and personal possessions not taken with patients during evacuation 	
10. Family/Responsible Party Notification	

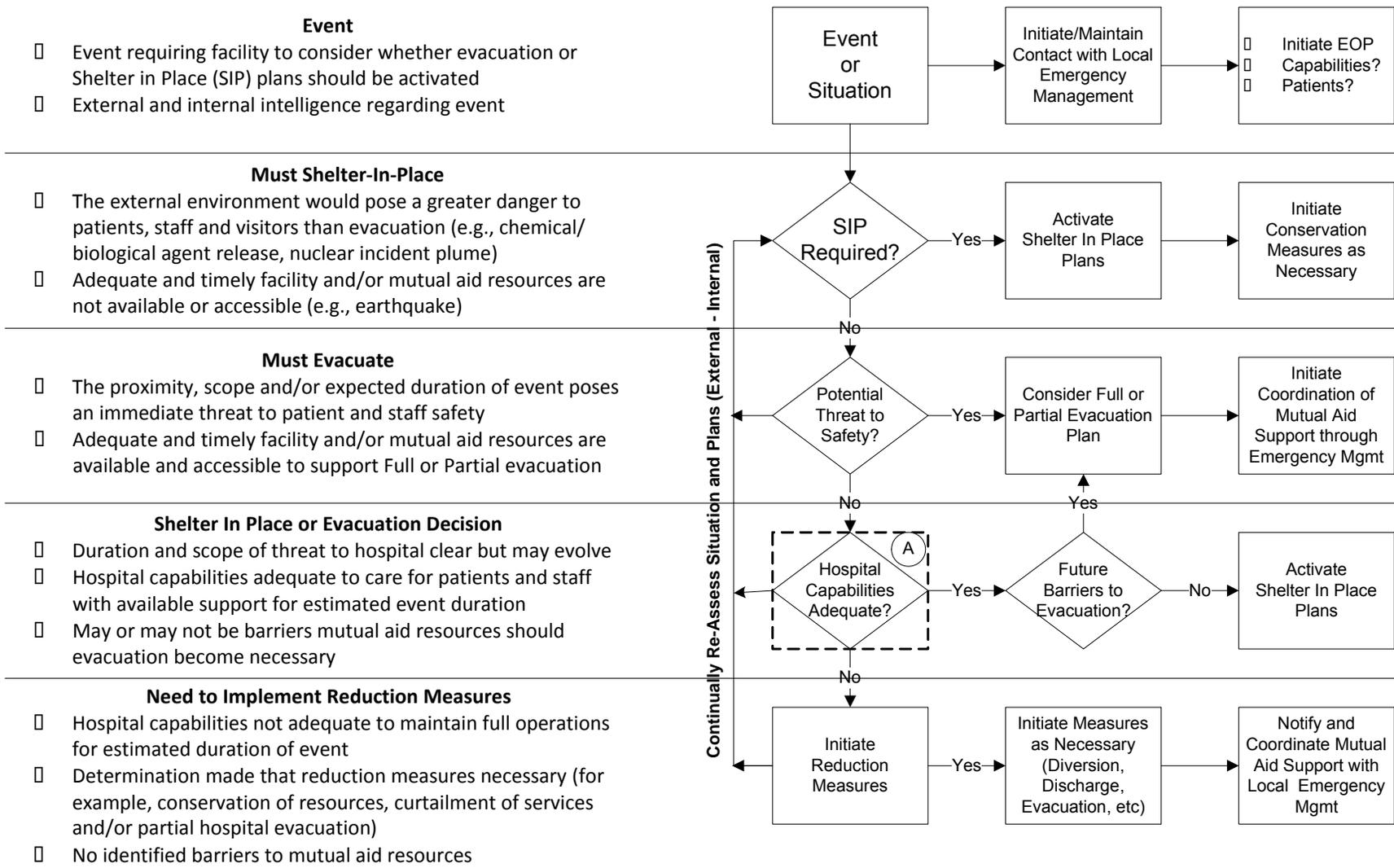
Note: this document does not represent a requirement for hospitals to reorganize their plans to coincide with the checklists; it is provided to assist hospitals in assessing and updating their evacuation plans. Rev: October 27, 2010

Template Element	Reference
<ul style="list-style-type: none"> Describe the process for assignment of staff members to conduct and track family/responsible party notification 	
<ul style="list-style-type: none"> Define the procedure to notify patient emergency contacts/family of an evacuation and the patient’s destination including protocols to communicate if initial contact attempts are not feasible or successful (e.g., Hot Line, Red Cross, Police, etc.) 	
11. Additional Governmental Agency Notification	
<ul style="list-style-type: none"> Protocol for emergency notification to public safety for immediate response must be clearly written and educated to staff 	
<ul style="list-style-type: none"> Protocol for emergency notification of patient evacuation to CDPH Licensing and Certification and Local Emergency Medical Services must be clearly written and educated to staff 	
<ul style="list-style-type: none"> Define position title responsible for maintaining contact numbers in an accessible location 	
12. Facility Evacuation Confirmation	
<ul style="list-style-type: none"> Define the protocol to verify that patient care and non-patient care areas have been evacuated (i.e. orange tags, chalk on door) 	
<ul style="list-style-type: none"> Define orientation and annual staff training for room evacuation provided to all staff 	
<ul style="list-style-type: none"> Describe how the protocols will be tested during drills and/or exercises 	
<ul style="list-style-type: none"> Describe the mechanism used to communicate the evacuation confirmation protocol to the responding fire department and other facility first responders 	
<ul style="list-style-type: none"> Describe the protocol to track and account for staff, visitors and non-employees (i.e., vendors, contractors) that may be on site during an evacuation 	
13. Transport of Records, Supplies and Equipment	
<ul style="list-style-type: none"> Describe the procedure for transport of Medication Administration Records (MARs) patient care/medical records 	
<ul style="list-style-type: none"> Describe measures taken to protect patient confidentiality 	
<ul style="list-style-type: none"> Describe the process to transport essential patient equipment and supplies 	
<ul style="list-style-type: none"> Define protocol for transfer of patient specific medications and records to receiving facility 	
<ul style="list-style-type: none"> Protocol for the transfer of patient specific controlled substances sent with patients and procedure to record receipt, full count and signature of transferring and receiving personnel 	
14. Recovery, Reopening and Repopulation of Evacuated Facilities	
<ul style="list-style-type: none"> Criteria and responsibilities for preparing facilities for reopening and assuring resources and ability to provide appropriate patient care 	
<ul style="list-style-type: none"> Steps to be taken to ensure a safe environment (e.g., facilities, fire and safety, etc., as appropriate). See <i>CHA Hospital Repopulation After Evacuation Guidelines and Checklist</i> 	
<ul style="list-style-type: none"> Process for securing government/regulatory agency approvals (e.g., Licensing and Certification, State Pharmacy Board) 	
<ul style="list-style-type: none"> Protocols for coordination and collaboration of transportation through County ICS (e.g., EMS DOC or EOC) or directly with transport vendors 	
<ul style="list-style-type: none"> Protocols for repatriation of staff and patients back to evacuated facilities, including facility access and staff identification, communication with receiving facilities, documentation, etc. 	
<ul style="list-style-type: none"> Protocols for communication with family regarding patient status/location 	
<ul style="list-style-type: none"> Protocols for communication and coordination with EMS ICS regarding status of facilities and repatriation/repopulation. 	

Source: CHA Hospital Preparedness Program modifications to San Diego HPP Workgroup checklist adapted and updated from the State of New York, Department of Health checklist published in November 2005.

Note: this document does not represent a requirement for hospitals to reorganize their plans to coincide with the checklists; it is provided to assist hospitals in assessing and updating their evacuation plans. Rev: October 27, 2010

Exhibit 1: Hospital Evacuation and Shelter In Place (SIP) Decision Tree



(A) Hospital Capabilities may include communication, resources (medical/non-medical supplies and equipment), utilities, staff, food, water, safety and security (including safety of facilities).

Attachment 4



California Board of Pharmacy Content Outline

For CPJE Examinations Taken On or After April 1, 2011

I. Patient Medications

25 Items

A. Organize and Evaluate Information

1. Obtain information from the patient/patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)
2. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)
3. Assess prescription/medication order for completeness, correctness, authenticity, and legality
4. Assess prescription/medication order for appropriateness (e.g., drug selection, dosage, drug interactions, dosage form, delivery system)
5. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments and/or diagnostic tests
6. Evaluate the pharmaceutical information needs of the patient/patient's representative
7. Assess prescription/medication order for insurance coverage

B. Dispense Medications

1. Enter prescription information into patient profile
2. Select specific product(s) to be dispensed for a prescription/medication order
3. Document preparation of medication in various dosage forms (e.g., compounded, unit dose)
4. Document preparation of controlled substances for dispensing
5. Verify label(s) for prescription containers
6. Select auxiliary label(s) for container(s)
7. Perform the final check of the medication prior to dispensing
8. Use automated dispensing equipment (e.g., Pyxis, Omnicell, Accu-Dose, ScriptPro)
9. Prepare finished dosage forms for dispensing (e.g., measure, count, reconstitute, compound, repackage, unit dose)

II. Patient Outcomes

30 Items

A. Determine a Course of Action

1. Determine desired therapeutic outcomes
2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary)
3. Assess changes in health status (e.g., onset of new disease states, changes in clinical condition)
4. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels)
5. Document monitoring and therapeutic management activities
6. Manage drug therapy according to protocols
7. Resolve problems that arise with patient's therapy (e.g., ADRs, drug interactions)

B. Educate Patients and Health Care Professionals

1. Assess the patient's understanding of the disease and treatment
2. Counsel patient/patient's representative regarding prescription medication therapy and devices
3. Counsel patient/patient's representative regarding nonprescription medication (OTC)
4. Counsel patient/patient's representative regarding herbal/complementary therapies
5. Counsel patient/patient's representative regarding non-drug therapy
6. Counsel patient/patient's representative regarding self-monitoring of therapy (e.g., devices, symptoms)
7. Verify the patient's/patient representative's understanding of the information presented
8. Educate health care professionals (e.g., physicians, nurses, medical residents/fellows, other health care providers/students, precepting intern pharmacists)
9. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
10. Respond to consumer inquiries (e.g. internet searches, media information, FDA patient safety alerts, radio/television commercials)
11. Provide supplemental information, as indicated (e.g., medication guides, computer generated information, videos)

III. Pharmacy Operations

20 Items

A. Procure Pharmaceuticals, Devices and Supplies, and Control Inventory

1. Place orders for pharmaceuticals, durable medical equipment, devices and supplies, including expediting of emergency orders
2. Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements (e.g., dangerous drugs, devices, supplies)
3. Maintain a record of controlled substances ordered, received, stored and removed from inventory
4. Dispose of expired or recalled pharmaceuticals, durable medical equipment, devices, supplies and document actions taken

5. Communicate changes in product availability (e.g., formulary changes, recalls, shortages) to pharmacy staff, patient/patient's representative, physicians and other health care professionals
6. Maintain policies and procedures to prevent theft and/or drug diversion

B. Perform Quality Assurance/Improvement

1. Assess pharmacist and/or pharmacy technician competence
2. Ensure the accuracy of medication administration
3. Participate in a system for medication error prevention, assessment, and reporting (e.g., root cause analysis, National Patient Safety Goals, medication error reduction program)
4. Participate in a system by which adverse drug reactions are documented, analyzed, evaluated and reported

C. Manage Operations, Human Resources and Information Systems

1. Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards/guidelines
2. Supervise the work of pharmacy staff
3. Ensure the availability, control, and confidentiality of patient and prescription information (e.g., patient profiles, medication administration records)

D. Manage Medication Use System

1. Maintain a formulary system
2. Apply therapeutic interchange
3. Conduct medication use evaluations

**TOTAL 90 questions
including 15 unscored pretest items**

Attachment 5

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	137	102	132	152	118	101							742
Pharmacist (initial licensing applications)	203	343	169	184	87	68							1054
Intern pharmacist	50	472	381	341	41	52							1337
Pharmacy technician	776	955	870	930	776	886							5193
Pharmacy	19	28	28	22	27	23							147
Pharmacy - Temp	10	5	10	25	15	9							74
Sterile Compounding	5	4	4	8	9	3							33
Sterile Compounding - Temp	0	0	0	0	5	2							7
Clinics	4	2	8	8	0	3							25
Hospitals	6	0	0	17	10	1							34
Hospitals - Temp	0	0	0	0	0	0							0
Nonresident Pharmacy	4	8	5	8	4	9							38
Nonresident Pharmacy - Temp	0	0	0	2	0	1							3
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	2	2	3	1	1	1							10
Nonresident Wholesalers	10	11	9	7	10	13							60
Nonresident Wholesalers - Temp	0	0	2	3	0	1							6
Wholesalers	7	9	6	3	9	3							37
Wholesalers - Temp	0	1	0	0	0	0							1
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0							0
Designated Representatives	36	42	39	49	25	32							223
Total	1269	1984	1666	1760	1137	1208	0	0	0	0	0	0	9024

*u/a denotes unavailable

** denotes corrected

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

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Issued													
Pharmacist	179	471	77	267	85	90							1169
Intern pharmacist	72	310	544	333	65	53							1377
Pharmacy technician	752	932	794	789	778	1042							5087
Pharmacy	21	18	23	17	28	26							133
Pharmacy - Temp	0	0	0	0	0	0							0
Sterile Compounding	3	1	1	3	3	10							21
Sterile Compounding - Temp	0	0	0	0	0	0							0
Clinics	9	6	3	1	3	5							27
Hospitals	1	2	0	3	7	10							23
Hospitals - Temp	0	0	0	0	0	0							0
Nonresident Pharmacy	4	0	10	6	4	6							30
Nonresident Pharmacy - Temp	0	0	0	0	0	0							0
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	2	0	2	2	1	1							8
Nonresident Wholesalers	4	3	4	7	14	6							38
Nonresident Wholesalers - Temp	0	0	0	0	0	0							0
Wholesalers	4	6	6	0	6	4							26
Wholesalers - Temp	0	0	0	0	0	0							0
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0							0
Designated Representatives	16	29	41	44	35	17							182
Total	1067	1778	1505	1472	1029	1270	0	0	0	0	0	0	8121
Pending													
Pharmacist Examination	725	566	622	605	498	487							605
Pharmacist Examination Eligible	1043	1043	979	799	825	760							799
Intern pharmacist	270	441	274	276	243	241							276
Pharmacy technician	2505	2550	2697	2693	2751	2465							2693
Pharmacy	75	81	85	90	86	80							90
Sterile Compounding	24	26	26	29	34	28							29
Clinics	29	26	23	28	26	24							28
Hospitals	8	8	6	13	23	13							13
Nonresident Pharmacy	43	51	40	44	44	46							44
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	12	15	12	11	11	11							11
Nonresident Wholesalers	78	86	74	72	69	76							72
Wholesalers	48	49	47	48	52	52							48
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Designated Representatives	188	197	180	175	163	181							175
Total	5048	5139	5065	4883	4825	4464	0	0	0	0	0	0	4883

r/u/a denotes unavailable

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Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11



*u/a denotes unavailable
** denotes corrected
*** denotes change in method of
collecting date effective 03/2010

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Change of Pharmacist-in-Charge***													
Received	104	128	102	154	108	106							702
Processed	118	132	99	136	123	90							698
Pending	389	385	388	381	366	463							381
Change of Exemptee-in-Charge***													
Received	8	9	6	12	8	12							55
Processed	4	0	7	0	0	0							11
Pending	108	117	116	128	136	148							128
Change of Permits													
Received	48	69	54	43	59	53							326
Processed	4	44	15	39	38	159							299
Pending	222	247	286	303	324	218							303
Discontinuance of Business***													
Received	20	21	10	24	17	78							170
Processed	0	0	28	1	0	78							107
Pending	135	156	138	162	179	179							162
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1572	1339	3322	2317	1052								9602
Pharmacy technician	2958	2262	4676	2504	1875								14275
Pharmacy	407	298	633	960	226								2524
Sterile Compounding	26	17	76	39	23								181
Clinics	106	68	145	91	47								457
Nonresident Pharmacy	31	20	70	18	18								157
Licensed Correctional Facility	0	0	27	17	2								46
Hypodermic Needle and Syringes	17	10	50	28	23								128
Nonresident Wholesalers	56	43	86	35	43								263
Wholesalers	73	27	91	27	37								255
Veterinary Food-Animal Drug Retailer	2	1	5	1	3								12
Designated Representative	155	113	416	179	170								1033
Total	5403	4198	9597	6216	3519	0	0	0	0	0	0	0	28933

*u/a denotes unavailable

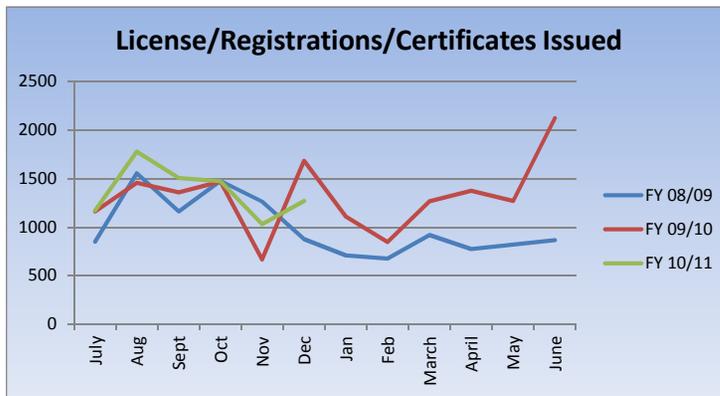
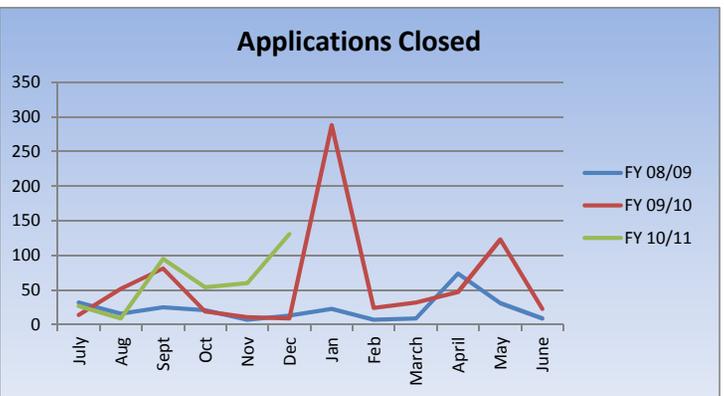
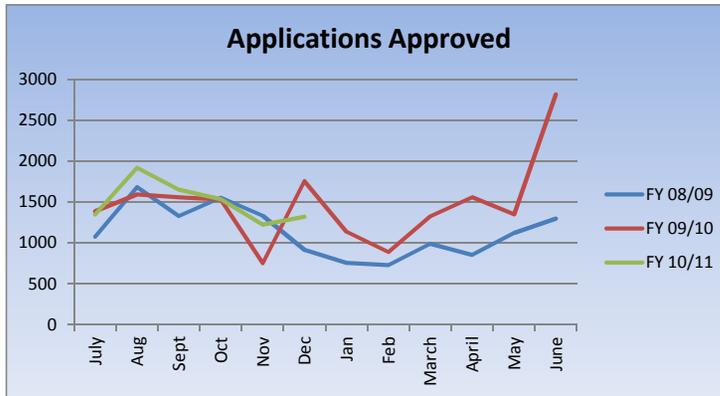
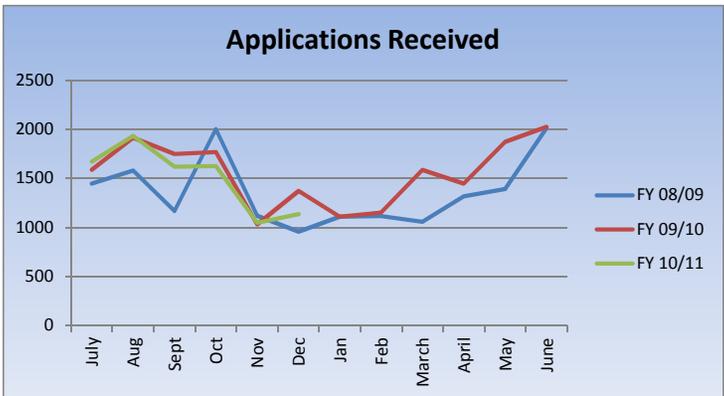
** denotes corrected

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

Attachment 6

**California Department of Consumer Affairs
Applications Received and Licenses Issued Statistics**

	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June	FY TOTAL
Pharmacy Board													
Applications Received FY 08/09	1448	1579	1168	2001	1118	956	1110	1116	1057	1317	1392	2012	16,274
Applications Received FY 09/10	1585	1914	1750	1767	1030	1373	1110	1152	1585	1447	1872	2025	18,610
Applications Received FY 10/11	1671	1933	1619	1626	1048	1134							9,031
Applications Approved FY 08/09	1075	1681	1325	1552	1331	912	753	725	986	850	1121	1297	13,608
Applications Approved FY 09/10	1387	1591	1555	1530	750	1756	1135	886	1323	1556	1347	2815	17,631
Applications Approved FY 10/11	1348	1921	1652	1534	1222	1320							8,997
Applications Closed FY 08/09	32	16	25	21	7	13	23	7	9	74	31	9	267
Applications Closed FY 09/10	14	52	81	19	11	9	288	24	32	47	123	23	723
Applications Closed FY 10/11	27	9	95	54	60	131							376
Licenses/Registrations/Certifications Issued FY 08/09	851	1556	1163	1477	1263	877	708	674	917	775	820	866	11,947
Licenses/Registrations/Certifications Issued FY 09/10	1163	1456	1359	1470	664	1685	1109	845	1267	1376	1270	2122	15,786
Licenses/Registrations/Certifications Issued FY 10/11	1172	1778	1506	1474	1029	1270							8,229



Attachment 7



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

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

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

DATE: December 2, 2010

LOCATION: Department of Consumer Affairs
El Dorado Room, 2nd Floor, N-220
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Public Member, Chair
Deborah Veale, RPh
Ryan Brooks, Public Member
Kenneth Schell, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Janice Dang, Supervising Inspector
Kristy Schieldge Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Debbie Anderson, Licensing Manager
Debi Mitchell, Licensing Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Lippe called the meeting to order at 1:37 p.m.

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

Background

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a

condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

Currently the board has over 240 such licensed facilities in California, and approximately 90 nonresident pharmacies with such permits.

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

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

There are three accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc (ACHC), 2. Community Health Accreditation Program (CHAP), and Det Norske Veritas (DNV). At the April 2010 Board Meeting, the board extended the accreditation of the first two agencies for one year while the board prepares a detailed review. At the July 2010 Board Meeting, the board added DNV as an accreditation agency, and approved it for three years.

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. At the beginning of 2010, the board modified its regulations for pharmacies that compound medication. Included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. These regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, took effect July 6, 2010. The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.

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

- 1. Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
- 2. Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.

3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Discussion

Supervising Inspector Janice Dang provided an overview of her assessment of the Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP). She provided a comparison of both agencies and reviewed site inspection results from 2 pharmacies for each agency. Dr. Dang indicated that the two pharmacies inspected from ACHC passed inspection. She discussed that the two pharmacies accredited by CHAP appeared to “ramp up” their standards for accreditation purposes and indicated that many corrections were issued based on the prior regulations.

The committee discussed these results. Tim Safley (ACHC) and Terry Duncome (CHAP) responded to questions from the committee.

Executive Officer Virginia Herold discussed that the board conducts random and unscheduled inspections.

Ms. Duncome provided that CHAP does conduct unannounced visits for facilities seeking exemption to licensure.

Debbie Veale asked how CHAP plans to address the results from the board's assessment.

Ms. Duncome provided that the results are a concern. She requested information regarding the two pharmacies that were inspected by the board in order to appropriately address their deficiencies. Ms. Duncome discussed that pharmacies that have identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated that the minimum number of visits for a facility is once every three years; but, annual inspections may be necessary based on a facility's performance.

Mr. Safley provided that all ACHC visits are unannounced.

Dr. Dang indicated that one pharmacy assessed by the board indicated that it was overdue for an accreditation review.

Ken Schell asked how many organizations CHAP accredits annually.

Ms. Duncome provided that CHAP accredits several hundred entities a year for all of the 10 services accredited. She indicated that CHAP accredits 13 pharmacies in California.

Dr. Schell asked if CHAP has identified critical findings in the past that have jeopardized licensure.

Ms. Duncome provided that these findings are not typical of the pharmacy program. She indicated that CHAP accredits 467 pharmacies in the US.

Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past five years.

Ms. Duncome discussed that a deferred status indicates that a facility has deficiencies that must be corrected prior to accreditation. She stated that accreditation can be denied or withdrawn. Ms. Duncome indicated that denial rates for CHAP accreditation are increasing.

Ms. Herold requested that CHAP and ACHC provide information to the board by January 10, 2011 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn, and denied within the last five years. She asked that the numbers reflect both national and California statistics and include nonresident pharmacies that are shipping into California.

Mr. Lippe asked if these findings will initiate a review of other California pharmacies accredited by CHAP.

Ms. Duncome provided that she will be requiring that all California pharmacies be reviewed.

Mr. Lippe asked how often similar findings occur.

Ms. Duncome provided that this is the first occurrence during her nine years as president of CHAP. She advised that CHAP has no deficiencies upon validation visits by the Centers for Medicare and Medicaid Services (CMS).

Dr. Schell requested that validation information be provided to the board.

Mr. Safley provided that ACHC is certified by the International Organization for Standardization (ISO). He agreed to provide this information to the board.

Ms. Veale asked how ACHC would respond if it received similar findings to that of CHAP.

Mr. Safley provided that ACHC would conduct an investigation to validate whether the accreditation should be revoked. He stated that the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a “dependant survey.”

Ms. Veale asked whether the board has the ability to provide investigation information to accreditation agencies.

Ms. Shellans advised that providing this information would make it public.

Ms. Herold indicated that both CHAP and ACHC have been approved accreditation agencies in California since 2003. She asked why neither agency has reported a substandard report to the board.

Mr. Safley provided that pharmacies are given 30 days to come into compliance. He stated that pharmacies that are found to be deficient with a state regulation will be reported to the board immediately.

Ms. Herold provided that the pharmacies accredited by ACHC were found to have some minor violations. She asked how ACHC will ensure compliance in these areas.

Mr. Safley provided that a plan of correction is required for minor violations. He stated that pharmacies will be placed on a “dependant status” for more significant violations and will be subject to a focus visit. He stated that any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status.

Dr. Schell requested statistics regarding revocation statuses from both agencies.

Ms. Duncome provided that pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit. She stated that accreditation will be revoked if the correction is not made by the third visit. Ms. Duncome explained that initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit.

No public comment was provided.

MOTION: Recommend to the board that ACHC and CHAP be reapproved as accreditation agencies for three years pending receipt of the requested information.

M/S: Schell/Veale

Support: 4 Oppose: 0 Abstain: 0

Additional Discussion

Ms. Herold advised that ACHC and CHAP should be prepared to provide a presentation to the full board at the February 2011 Board Meeting. She encouraged both agencies to conduct annual inspections of the pharmacies they accredit.

Dr. Dang reviewed a response from the Joint Commission that had been requested by the board at the October 2010 Board Meeting regarding survey teams that include a pharmacist and their findings.

Ms. Herold advised that she will request that this response be refined to answer the questions specified by the board.

There was no additional public comment.

2. Update on the Board's Psychometric Evaluation for the ExCPT and PTCB Examinations

Background

Business and Professions Code 139 requires a psychometric assessment description of the occupational analysis serving as the basis for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Chair Report

Chair Lippe provided that the department's Office of Professional Examination Services will be conducting these evaluation assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT) for the board.

Chair Lippe provided that upon completion, the committee will be advised of the findings at which time it may recommend a change to the statutory requirements for licensure detailed in B&PC 4202.

Discussion

Ms. Veale asked if there is an expected date of completion for the evaluation.

Ms. Herold provided that the evaluation should be completed in June 2011. She discussed some of the challenges encountered in trying to secure an evaluator as the state requires that this work be done by a state employed psychometric evaluator.

Ms. Herold advised that the PTCB has never been validated by California. She suggested that the board consider adding both exams to the law book if they both meet minimum standards.

Public Comment

A member of the public sought clarification regarding externship requirements for pharmacy technician students.

Ms. Shellans provided that this item must be requested as an agenda item for a future meeting for discussion.

3. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Chair Report

Chair Lippe provided that at several prior meetings of the board or its committees, including the last two meetings of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. He discussed that specific areas are required in other disciplines.

Discussion

Ms. Herold provided 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.

Dr. Schell discussed the challenge of evaluating course content to ensure it is achieving the objective. He stated that certain content may not be relevant or applicable to all pharmacists in all areas of practice.

Ms. Veale suggested that the CE hour requirement be broken down into required subjects and discretionary subjects. She explained that a licensee will be required to complete the specified hours of the required subjects; but, can choose relevant subjects from 3 main categories that relate to their practice to complete the remaining discretionary hours. Ms. Veale indicated that the licensee will be required to certify that they have completed these hours and will be subject to random audits.

Mr. Brooks suggested that the board contract with a vendor to provide online courses.

Ms. Shellans reviewed the litigation issues and challenges involved with securing such a contract through the states contracting process. She indicated that it would be more efficient to establish minimum standards for course content that course providers would be required to follow.

Ms. Herold provided that to establish such a requirement would require either a legislative or regulation change.

Mr. Brooks suggested that staff research possible providers in this area and conduct a review of necessary implementation.

Ms. Shellans recommended that the committee request direction from the board regarding whether specific content areas for CE should be pursued. She stated that if approved, the committee can determine implementation.

Dr. Schell left the meeting room at 2:58 p.m.

No public comment was provided.

MOTION: Recommend that the board pursue specific content areas for continuing education. If recommendation is approved, authorize staff to investigate implementation.

M/S: Veale/Brooks

Support: 3 Oppose: 0 Abstain: 0

4. Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists

Background

Earlier this year, the board established new requirements for pharmacist renewal that were placed into CCR Section 1701. This regulation was approved by the Office of Administrative Law and is scheduled to take effect on December 7, 2010.

The regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The board was advised the beginning of November that due to the on-going fiscal crisis and hiring restrictions within State government, effective Monday, November 8, 2010, the California Department of Justice (DOJ) no longer has the resources to take phone calls or process follow-up inquiries from regulatory entities who have submitted a criminal offender record information search request through the DOJ or the Federal Bureau of Investigation (FBI).

Board staff requested intervention by the department as its impact affects all boards and bureaus within the department. The board has not received any information thus far.

Chair Report

Chair Lippe provided that the board's efforts to coordinate with the DOJ to establish the necessary changes required to implement these requirements have been unsuccessful.

Discussion

Ms. Herold provided that the board has experienced opposition in allowing the coding for different licensure types and distinguishing those from reprints. She discussed the workload involved with identifying prints and matching them to the appropriate applicant.

Dr. Schell returned to the meeting room at 3:02 p.m.

Chair Lippe suggested the use of a colored envelope to be used in the mailing of reprints.

Ms. Herold discussed that the board does not process its own renewals. She stated that a system is needed that will allow for audit validation.

Dr. Schell left the meeting at 3:06 p.m.

Public Comment

A member of the public sought clarification regarding accurate submission of Livescan prints.

Licensing Manager Debi Mitchell discussed several factors impacting Livescan accuracy including operator error, print quality, and incorrect information. She recommended that the scan and appropriate information including social security number be reviewed by the licensee or applicant before it is submitted by the operator. She advised that if a deficiency letter is sent, the licensee or applicant needs to ensure that this area is corrected.

Ms. Herold provided that her offer to help the DOJ in this process was denied.

5. Discussion of the California Hospital Association's Repopulation After Hospital Evacuation Guidelines and Checklist

Chair Report

Chair Lippe provided that Executive Officer Herold recently served on a panel convened by the California Hospital Association to identify the components needing check off following the evacuation of the hospital but before the hospital can be "repopulated." He indicated that the California Department of Public Health (CDPH) also participated.

Discussion

Ms. Herold discussed that several agencies are involved in the event a hospital needs to be repopulated. She stated that with respect to the pharmacy, if called upon by the CDPH, the board will inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs.

Mr. Brooks asked how quickly the board would perform an inspection.

Ms. Herold provided that CDPH or the hospital would contact the board to request an inspection. She indicated that the CDPH makes the determination whether a facility is clear for repopulation, as such, the board's role is relatively minor in this process.

No public comment was provided.

6. Competency Committee Report

Discussion

Ms. Herold provided that each Competency Committee workgroup met once in the fall of 2010 for examination development. She stated that development is going well.

No public comment was provided

7. Update on the Conversion to a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists in April 2011

Discussion

Ms. Herold provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the CPJE examination. She stated that to complete this analysis, the committee developed a job analysis survey with the board's contracted psychometric firm. Ms. Herold advised that the results of this survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California.

Ms. Herold provided that under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline, which was presented to the board at the April 2010 Board Meeting. She stated that after the board approved the revised content outline, the Competency Committee worked with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Ms. Herold provided that the new outline and new sample questions will be posted on the board's Web site. She discussed that this typically triggers anxiety for applicants and a delay in their taking the exam which consequently delays the release of the results.

Ms. Veale asked whether applicants will be notified.

Ms. Herold indicated that notification can be provided.

Ms. Veale discussed that the changes are intended to remove duplicity with the NAPLEX exam.

No public comment was provided.

8. Licensing Statistics

Discussion

Ms. Herold reviewed the licensing statistics provided in the committee packet showing the applications received, licenses issued, applications pending and renewals processed since the beginning of the fiscal year. She discussed that these statistics are impacted by the vacancies that have not been filled due to the hiring freeze.

Mr. Brooks expressed concern regarding the hiring freeze considering the fact that the board does not use the general fund.

Ms. Herold discussed that despite being special funded, the board is not exempt to hiring freezes.

The committee discussed the impact on licensees as they are paying fees for services that are impacted by the hiring freeze.

No public comment was provided.

9. Workload and Processing Statistics

Discussion

Ms. Herold reviewed the following current application and mail processing times:

	<u>Applications</u>	<u>Incoming Mail</u>
Pharmacist Exam	14 days	5 days
Pharmacist Intern	5 days	4 days
Pharmacy Technician	55 days	16 days
Site Permits	20 – 60 days	20 days
Change of Permits	150 days	
DOBs	60 days	
Change of PIC	60 days	
Change of DRIC	40 days	

Ms. Herold discussed that these processing times were significantly impacted by the furloughs and the current hiring freeze. She indicated that exemption requests have been submitted; but, have not been acted on.

Licensing Manager Debbie Anderson reviewed the processing procedure. She stated that processing is done in batches and that managers will lend assistance for

processing times longer than 60 days. Ms. Anderson indicated that a quarterly inventory is conducted to ensure appropriate processing.

Mr. Brooks sought clarification regarding electronic submission of applications.

Ms. Anderson indicated that the department is in the development stages for this process. She discussed the BreEZe system and the extensive implementation process involved.

No public comment was provided.

10. Public Comment for Items Not on the Agenda

A member of the public discussed the prevalence of calculation errors. She suggested that a math component be considered as a CE subject.

Ms. Herold stated that this is a significant competency issue. She encouraged this activity be reported to the board.

Ms. Veale suggested that the board consider this topic during the board discussion on specific content areas for CE during the February 2011 Board Meeting.

The meeting was adjourned at 3:36p.m.

Attachment 8

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within three work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
		# of Apps. Received:				Average Days to Process:			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	371	371			35	10		
	Pharmacist (initial licensing)	715	339			4	4		
	Pharmacy Intern	903	434			9	5		
	Pharmacy Technician	2,601	2,592			28	48		
	Pharmacies	81	100			16	29		
	Non-Resident Pharmacy	17	21			28	31		
	Wholesaler	22	15			25	31		
	Veterinary Drug Retailers	0	0			0	0		
	Designated Representative	117	106			24	31		
	Out-of-state distributors	30	30			24	35		
	Clinics	14	11			16	26		
	Hypodermic Needle & Syringe Distributors	7	3			13	20		
	Sterile Compounding	13	20			12	37		
	Change of Permit	171	155			45	71		
	Pharmacist in Charge	334	368			19	57		
	Designated Representative in Charge	23	32			45	57		
	Discontinuance of Business	51	102			66	68		

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

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	5	3		
Pharmacist (initial licensing)	7	3		
Pharmacy Intern	7	3		
Pharmacy Technician	14	15		
Pharmacies	8	12		
Non-Resident Pharmacy	4	11		
Wholesaler	4	11		
Veterinary Drug Retailers	4	0		
Designated Representative	4	11		
Out-of-state distributors	4	11		
Clinics	8	12		
Hypodermic Needle & Syringe	4	11		

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

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

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

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	272	442		
Pharmacy Intern	926	451		
Pharmacy Technician	2,478	2,609		
Pharmacies	65	91		
Non-Resident Pharmacy	14	16		
Wholesaler	16	10		
Veterinary Drug Retailers	0	0		
Designated Representative	86	96		
Out-of-state distributors	11	27		
Clinics	18	9		
Hypodermic Needle & Syringe	4	4		
Sterile Compounding	5	16		

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	81	125		
Pharmacies	2	0		
Non-Resident Pharmacy	5	0		
Clinics	3	0		
Sterile Compounding	0	1		
Designated Representative	12	11		
Hypodermic Needle & Syringe	3	0		
Out-of-state distributors	19	0		
Wholesaler	5	2		
Veterinary Drug Retailers	0	0		
Registered Pharmacist	155	212		
Intern Pharmacist	1	1		

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

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	2	3		
Intern Pharmacist	0	2		
Pharmacy Technician	21	23		
Pharmacies	0	2		
Non-Resident Pharmacy	1	0		
Clinics	0	0		
Sterile Compounding	0	0		
Designated Representative	0	0		
Hypodermic Needle & Syringe	0	0		
Out-of-state distributors	0	1		
Wholesaler	0	0		

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

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	645	565		
Pharmacy Technicians	498	856		
Site licenses (pharmacy, clinics)	1,284	469		
Site licenses (wholesalers, nonresident pharmacies)	925	1,000		
Pharmacist in Charge	219	96		
Renewals	269	310		

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	82	*		
Pharmacy Technicians	*	*		
Site licenses (pharmacy, clinics)	369	256		
Site licenses (wholesalers, nonresident pharmacies)	221	114		
Pharmacist in Charge	49	52		
Renewals	1,138	1,329		

* Voicemail status requests have been suspended to allow staff time to focus on processing applications and issuing licenses

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.								
Measure:	Percentage of revenue cashiered application within 2 working days.								
Tasks:	Revenue Received:				Average Days to Process:				
	Qtr 1	Qtr 2*	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
	Applications	\$676,974	\$407,028			3	2.5		
	Renewals	\$2,912,806	\$1,363,553			3	2.5		
	Cite and Fine	\$325,040	\$232,210			4	3		
	Probation/ Cost Recovery	\$30,869	\$52,981			4	3		
	Request for Information/ License Verification	\$5,005	\$5,735			3	2.5		
	Fingerprint Fee	\$17,432	\$11,378			3	3		
* 2nd quarter reflects October and November 2010 data available at the time of report development.									

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.																																													
Measure:	Percentage of licensing records changes within five working days.																																													
Tasks:	<table border="1"> <thead> <tr> <th data-bbox="370 367 743 415"></th> <th colspan="4" data-bbox="743 367 1143 415">Requests Received:</th> <th colspan="4" data-bbox="1143 367 1523 415">Average Days to Process:</th> </tr> <tr> <th data-bbox="370 415 743 443"></th> <th data-bbox="743 415 857 443">Qtr 1</th> <th data-bbox="857 415 954 443">Qtr 2</th> <th data-bbox="954 415 1052 443">Qtr 3</th> <th data-bbox="1052 415 1143 443">Qtr 4</th> <th data-bbox="1143 415 1240 443">Qtr 1</th> <th data-bbox="1240 415 1338 443">Qtr 2</th> <th data-bbox="1338 415 1435 443">Qtr 3</th> <th data-bbox="1435 415 1523 443">Qtr 4</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 443 743 491">Address/Name Changes</td> <td data-bbox="743 443 857 491">3,120</td> <td data-bbox="857 443 954 491">2,606</td> <td data-bbox="954 443 1052 491"></td> <td data-bbox="1052 443 1143 491"></td> <td data-bbox="1143 443 1240 491">5</td> <td data-bbox="1240 443 1338 491">3</td> <td data-bbox="1338 443 1435 491"></td> <td data-bbox="1435 443 1523 491"></td> </tr> <tr> <td data-bbox="370 491 743 569">Off-site Storage Applications (approved)</td> <td data-bbox="743 491 857 569">24</td> <td data-bbox="857 491 954 569">26</td> <td data-bbox="954 491 1052 569"></td> <td data-bbox="1052 491 1143 569"></td> <td data-bbox="1143 491 1240 569">20</td> <td data-bbox="1240 491 1338 569">25</td> <td data-bbox="1338 491 1435 569"></td> <td data-bbox="1435 491 1523 569"></td> </tr> <tr> <td data-bbox="370 569 743 621">Transfer of Intern Hours to Other States</td> <td data-bbox="743 569 857 621">34</td> <td data-bbox="857 569 954 621">17</td> <td data-bbox="954 569 1052 621"></td> <td data-bbox="1052 569 1143 621"></td> <td data-bbox="1143 569 1240 621">30</td> <td data-bbox="1240 569 1338 621">30</td> <td data-bbox="1338 569 1435 621"></td> <td data-bbox="1435 569 1523 621"></td> </tr> </tbody> </table>		Requests Received:				Average Days to Process:					Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Address/Name Changes	3,120	2,606			5	3			Off-site Storage Applications (approved)	24	26			20	25			Transfer of Intern Hours to Other States	34	17			30	30		
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Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 216 1490 510"> <p>1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.</p> <li data-bbox="370 510 1490 699"> <p>2. Evaluate the drug distribution system of clinics and their appropriate licensure. <i>1st Qtr 09/10:</i> Continued to advise clinics and their advocates about the barrier the Capen decision places on surgicenters/clinics from obtaining a board clinic permit. A legislative solution is needed. <i>3rd Qtr 09/10:</i> Board hears presentation by Fort Sutter Surgery Center discussing the issue.</p> <li data-bbox="370 699 1490 951"> <p>3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure.</p> <li data-bbox="370 951 1490 1392"> <p>4. Work with local and state officials on emergency preparedness and planning for pandemics and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>2nd Qtr 09/10:</i> Board votes that in declared emergencies where a board meeting cannot quickly be scheduled, a subcommittee of three members can make decisions for patient safety under provisions of Business and Professions Code section 4062 and the board's emergency response policy. <i>4th Qtr 09/10:</i> Licensing continued reviewing requests from CDPH seeking clarification on board disaster response policy. <i>2nd Qtr 10/11:</i> Discussion of the California Hospital Association's repopulation after hospital evacuation guidelines and checklist at Licensing Committee Meeting.</p> <li data-bbox="370 1392 1490 1505"> <p>5. Evaluate the need to issue a provisional license to pharmacy technician trainees. <i>Dec. 2010:</i> Update on the board's psychometric evaluation for the ExCPT and PTCB at the Licensing Committee.</p>

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

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

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

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

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

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

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

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

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

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

2nd Qtr 10/11: *DCA psychometric expert initiates review of PTCB and ExCPT exams.*

7. Review requirements for qualifications of pharmacy technicians with stakeholders

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

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

Board participates in CSHP sponsored stake holder meeting.

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

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

8. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.
- Note:** I-Licensing system has been cancelled and the BreEZe system will take its place.
- July 2006:* Board executive officer becomes executive sponsor of program.
- Nov. 2006:* Board completes system identification of parameters for each licensing program.
- Dec. 2006 - Jan. 2007:* Preparatory work and pilots completed; board staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.
- 3rd Qtr 08/09:* Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward. ATS project implemented.
- 2nd Qtr 09/10:* Board advised of new initiative to facilitate online applicant submission and renewal.
- 4th Qtr 09/10:* Board analyst temporarily assigned to assist on BreEZe project.
- 1st Qtr 10/11:* Assistant Executive Officer chairs forms design workgroup to consolidate forms for all boards (reducing programming costs). Executive Officer and Assistant Executive Officer continue on BreEZe execution steering committee.
- 2nd Qtr 10/11:* Board analyst continues to work with the department on the BreEZe project.
9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.
- 3rd Qtr 06/07:* Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).
- Oct. 2007:* Board considers basic internship competencies developed under the program and develops letter of support.
- Oct. 2008:* California Pharmacy Council meets to discuss Intern requirements.
- Dec. 2009:* Licensing Committee again discusses the requirements given that other states are no longer transferring intern hours.

- 10. Implement new test administration requirements for the CPJE.**
- March 2007:* Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.
- June 2007:* Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.
- 4th Qtr 09/10:* Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
- 2nd Qtr 07/08:* Transition efforts to PSI continue.
- 3rd Qtr 07/08:* New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.
- 1st Qtr 09/10:* Competency Committee develops occupational analysis survey.
- 2nd Qtr 09/10:* Competency Committee develops new content online for CPJE.
- 3rd Qtr 09/10:* Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
- 2nd Qtr 10/11:* Documents advising applicants of new exam structure developed and released.
- 3rd Qtr 10/11:* Board staff prepares to update CPJE Candidate Information Bulletin and Web site for new Content Outline effective April 1, 2011.
- 11. Participate in ACPE reviews of California Schools of Pharmacy.**
- Oct. 2007:* Board participates in review of California Northstate College of Pharmacy.
- Jan. 2008:* Board participates in review of UCSF.
- March 2008:* Board participates in review of Touro.
- 3rd Qtr 08/09:* Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.
- 3rd Qtr 09/10:* Board participates in ACPE review of the school of pharmacy at UOP.
- 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training.**
- Sept. 2007:* Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.
- Oct. 2007:* Board evaluates options for training of designated representatives.
- Sept. 2008:* Licensing Committee hears testimony regarding program.
- June 2009:* Evaluation of designated representative training scheduled for September.

- 13. Convene Committee to evaluate drug distribution within hospitals.**
2nd Qtr 08/09: Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.
3rd Qtr 08/09: Board establishes subcommittee to initiate review.
March 2009: First meeting convened.
June 2009: Second meeting convened in San Francisco.
Sept. 2009: Third meeting convened in Sacramento.
Dec. 2009: Work of Hospital Subcommittee nearly completed. Board to review parameters for recalls at January 2010 meeting.
2nd Qtr 09/10: Document finalized.
- 14. Improve reporting of and accounting for intern hours.**
4th Qtr 08/09: Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.
- 15. Participate in initiatives to increase the number of pharmacists in California to meet demand.**
4th Qtr 08/09: Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.
- 16. Assess the operations of specialty pharmacy services.**
4th Qtr 08/09: Board initiates review of refill pharmacies.
2nd Qtr 10/11: Board considers request from PETNET Solutions for a waiver of security requirements for pharmacies to permit after hours maintenance of equipment without a pharmacist present. The board lacks the authority to waive California pharmacy law in the manner requested.
- 17. Encourage use of technology where it benefits the public.**
June 2009: Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.
Oct. 2009: Automation equipment demonstrated to Board that would facilitate unit dose packaging in hospitals and allow for barcoding.
Jan. 2010: Demonstration to Board of patient medication instructions in various languages accessible by emerging software available to pharmacies.
- 18. Secure the implementation of e-prescribing in California by the earliest possible date.**
4th Qtr 08/09: Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.
2nd Qtr 10/11: Board hears presentation by CalERx on the status of e-prescribing in California.
Executive Officer provides presentations on e-prescribing at annual CalERx meeting.
Board establishes an ad hoc task force to develop a guidance document on the e-prescribing of controlled substances.

- 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.**
- 4th Qtr 08/09: Board assists the California Department of Public Health in responding to distribution of Tamiflu and Relenza. Pharmacy law requirements regarding labeling and dispensing not waived as standard and necessary pharmacists care could still be provided.*
- 2nd Qtr 09/10: Board continues to work with Department of Public Health on H1N1 distribution issues.*
- 20. Automate fingerprint background results with the Department of Justice.**
- 2nd Qtr 09/10: Began working with the DCA to implement automation of background results for applicants to be automatically imported into the board's Applicant Tracking System (ATS).*
- 3rd Qtr 09/10: Continued working with the DCA on developing programming specifics in order to go live on February 17, 2010. Board staff develops the procedures.*
- 4th Qtr 09/10: Final revision to the procedures, trained staff, and assigned job task to staff. Board staff continues to manage automated process and resolve issues.*
- 21. Evaluate pharmacy technician, pharmacist, and intern pharmacist application process to identify areas for improvement and to modify the application requirements to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB).**
- 3rd Qtr 09/10: Staff reached out to pharmacy technician programs to advise them of statutory changes to the application fee. Staff revised pharmacy technician application after reviewing most common deficiencies for legal review.*
- 4th Qtr 09/10: Staff reached out to pharmacy technician programs educating them on the most common application deficiencies.*
- 1st Qtr 10/11: Staff finalized the draft pharmacy technician, pharmacist, and intern pharmacist application. Legal approved the draft pharmacy technician and intern pharmacist application.*
- 2nd Qtr 10/11: Legal approved the pharmacist application. Proposal to initial a regulation change to update the pharmacy technician application at the Licensing Committee meeting. Licensing Committee made recommendations for board to pursue the changes to the pharmacy technician application. Licensing Committee made recommendations for board to pursue the changes to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB) for the pharmacy technician, pharmacist, and intern pharmacist application for licensure. At the recommendation of the Licensing Committee, the board authorized the Executive Officer to take all steps necessary to initiate a rulemaking update the pharmacy technician application form and NPDB/HIPDB self-query report.*

- 22. Implement Fingerprint Requirement for Pharmacist Renewal.**
*4th Qtr 09/10: Regulation approved by Office of Administrative Law (effective date of regulation is December 7, 2010).
 Department drafted programming changes to accommodate requirement. Board staff tested changes in a testing environment.*
*2nd Qtr 10/11: Obtained FBI approval through DOJ for job title on Live Scan for licensed pharmacists.
 Board staff working with the department to implement importing automated fingerprint response into ATS.
 Implementation delayed due to hiring freeze and approval by FBI of new category for reprinted pharmacists.*
- 23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership.**
4th Qtr 09/10: Board staff developed standards for common ownership requirements.
- 24. Evaluate Continuing Education Requirement for Pharmacists**
*2nd Qtr 10/11: Board discussed a proposal to specify continuing education credit for pharmacists in specific content areas and forwarded to Licensing Committee.
 Licensing Committee discussed multiple specific areas for optional continuing education. The committee decided to amend the regulation 16CCR 1732.2. to allow for continuing education hours for various specified activities.
 Regulation 16CCR 1732.2. was noticed for public comment on Nov. 22, 2010.*
- 25. Improve pharmacy Technician application forms to reduce deficiencies.**
*1st Qtr 10/11: Identify changes and initiate rulemaking process to adopt changes to application forms.
 2nd Qtr 10/11: Additional enhancements identified, and returned to board for adoption.*
- 26. Require a self query HIPDB report as a condition for applying for a pharmacy technician or pharmacists intern license and as part of the application process to take the CPJE.**
1st Qtr 10/11: Board approves concept and staff readies regulation changes to implement.