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

Licensing Committee Report

Members:

Greg Lippe, Public Member, Chairperson
Ryan Brooks, Public Member
Ramón Castellblanch, PhD, Public Member
Debbie Veale, PharmD
Tappan Zee, Esq., Public Member

LICENSING COMMITTEE REPORT AND ACTION

Report of the Meeting held on June 16, 2010.

a. **FOR DISCUSSION: Request for Board Recognition of a School of Pharmacy with Precandidate Status**

Attachment 1

Background

Business and Professions Code Section 4208 (a)(1) authorizes the board to issue an intern pharmacist license to a person who is currently enrolled in a school of pharmacy recognized by the board.

Tile 16 CCR section 1719, states that a “recognized school of pharmacy” means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE).

Request

The University of New England College of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications.

University of New England College of Pharmacy is eligible for advancement to candidate accreditation status. A program that achieves candidate accreditation status can remain in this status from 2-4 years before advancing to full accreditation status. Historically, pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

Attachment 1 contains a copy of the request from the University of New England College of Pharmacy requesting recognition by the board.

Committee Discussion/Action

Recommend to the board recognition of the University of New England, College of Pharmacy, Portland, Maine.

Post Meeting Update

During its July 2010 Board of Directors Meeting, the ACPE Board voted to grant the University of New England College of Pharmacy candidate status through June 30, 2011. Given this, this university now falls within the definition of a school of pharmacy recognized by the board in CCR section 1719. No board action is required.

b. FOR DISCUSSION and POSSIBLE ACTION: Discussion of Proposed Changes to the Intern Hours Requirements for California

Attachment 2

Background

Over the last few years, the Licensing Committee has considered proposals to amend the intern hour requirements. The committee has also discussed major changes to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. These new requirements added hours to the educational requirements students need as part of their intern training and are required as a condition for a school to maintain its accreditation status with the ACPE. Each time the committee has decided not to recommend changes to the board.

Under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California. (Business and Professions Code Section 4200.)

Additionally, Section 1728 of the California Code of Regulations specifies that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. The remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically earned within a pharmacy. California pharmacy students typically earn the 600 “discretionary” hours for school-related experiential training (clinical clerkship).

Request

Recently board staff received a new proposal to modify the intern hour requirements. The proposal requests that the board change the current requirement to allow 900 intern hours to be accrued within a school of pharmacy and reduce the minimum number of pharmacy experience hours to 600. The proposal states that UCSF’s current curriculum includes more than 1000 hours of advanced pharmacy practice.

Attachment 2 contains a copy of the proposal for UCSF, CCR section 1728 and an overview of prior discussions related to intern hours.

Should the board vote to approve the request by UCSF, an amendment to CCR section 1728 would be necessary to implement.

Committee Discussion/Recommendation

The committee discussed this issue and heard public comment. Discussion during the meeting included that such a change could have a detrimental impact. The committee did not take any action on this item.

UCSF did not have a representative at the Licensing Committee Meeting; however, one will be present at the board meeting.

c. **FOR INFORMATION: Review of Data Describing the Board of Pharmacy's Audits of Continuing Education Earned by Pharmacists as a Condition of Renewal**

Attachment 3

Background

Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education during each renewal cycle. In 2009, this section was amended to also allow the board to convert the renewal to an inactive license if the pharmacist fails to provide such documentation when requested. (A pharmacist with an inactive license cannot work as a pharmacist in California.)

At the time of renewal, every pharmacist must certify under penalty of perjury that he or she has completed the 30 units.

The exact language a pharmacist is asked to certify is:

I certify that I have completed _____ hours of continuing education during my last renewal period. I declare under penalty of perjury under the laws of the state of California that the foregoing is true and correct.

Signature

Date

The board periodically audits a few pharmacists each month to determine their compliance with this requirement. If they are unable to provide 30 hours of CE for the renewal period, they are directed to immediately provide proof of completion of additional CE now (earned outside the renewal period, but to bring them into compliance) and then are cited and fined.

The results of recent board audits indicates that 16 percent of those audited could not provide proof of completion of continuing education credits earned during the last renewal period. Of these, 5 (2 percent) ended up having their licenses converted to inactive status. Month by month audit results are provided in **Attachment 3** along with a copy of B&PC section 4231.

Committee Discussion/Action

The committee discussed the current CE process as well as possibly identifying target areas for such education. It was the consensus of the committee to recommend that the full board discuss the topic of targeted CE. Direction was given to staff to establish parameters in this area. Work has not yet started on establishing these parameters.

d. **FOR ACTION: Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include “Self-Query” Reports from the Healthcare Integrity and Protection Data Bank (HIPDB)**

Attachment 4

Background

B&PC Section 4207 requires the board to make a thorough investigation to determine whether an applicant is qualified for the license being sought and authorizes the board to request any information it deems necessary to complete the investigation required.

CCR Section 1728 established the requirements for pharmacist licensure examination.

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

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

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

Proposal

Board staff proposes a change to the application requirements to also include a “self-query” report to be required as part of the application process. Requiring such a search will ensure that the board has all relevant information when making a licensing decision and does not inadvertently issue a pharmacist or intern license to an individual that has been disciplined in another state unless, after review of the information, it determines that such an issuance is consistent with the board’s consumer protection mandate.

Attachment 4 contains a fact sheet from HIPDB on the self-query process as well as a list of the professional licenses that are contained within the databank. A review of other jurisdictions indicates that several other states are integrating the “self-query” into their licensing requirements for varying health care providers.

Committee Discussion/Action

Recommend that the board take action on this item to adopt the “self-query” report requirement.

e. **FOR DISCUSSION and POSSIBLE ACTION: Emergency and Disaster Response Planning Update**

Attachment 5

Background

In 2007, the board developed and released an emergency response policy, pursuant to California Business and Professions Code section 4062 to waive statutory requirements to benefit public safety in response to a declared emergency or disaster. A copy of the policy is provided in **Attachment 5**.

In 2009, the section was amended to add subdivision (c) to provide for use of temporary facilities during declared emergencies. (A copy of B&PC 4062 is provided in **Attachment 5**.)

At the October 2009 Board Meeting, the board voted that in situations following a declared emergency or disaster where the board cannot convene a meeting timely, the board delegates its authority to waive statutory requirements to benefit public safety to a committee of three board members via teleconference.

MOTION: In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., e-mail), or by other means of communication to exercise the powers delegated to full board pursuant to Business and Professions Code section 4062.

Request

Recently the California Department of Public Health requested clarification on several issues surrounding the board policy.

1. How will the board know when to rescind its emergency suspension of the requirements under these provisions once the emergency has ended?
2. What is the trigger for the emergency to be dissipated and have the licensees return to practice?
3. Who initiates and when does it go into place?

The Executive Officer provided the following response:

There is not a definitive answer. Often there is a point where either the Governor or the Office of Emergency Services makes a statement that the emergency is over. The California Department of Public Health, I would suspect, would also be a likely agency to note when the emergency has dissipated. At some point, business and patients return to normal. This is the point when the board would advise entities to return to normal business practices. In the limited instances where the board used its emergency policy (several years ago during CA's wildfires), we did not need to issue notice about the end of the emergency. Things returned to normal on their own

Committee Discussion/Action

The committee chair indicated that the board may wish to discuss and amplify this response, and develop its policy about criteria for ending the emergency authorization. The

committee consensus was to discuss this issue during the July 2010 Board Meeting and to establish parameters for mobile pharmacies.

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

Attachment 6

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

The most recent quality assurance review of the CPJE ended around June 24, 2010.

Attachment 6 contains the pass rate for the CPJE from October 1, 2009 through March 31, 2010. Also provided is a five year pass rate comparison for the CPJE and NAPLEX exam.

Job Analysis and Content Outline for the CPJE

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. To complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. The information learned from 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 has worked on revising its content outline and the completed work was presented to the board at the April 2010 Board Meeting. During this meeting, the board reviewed and approved the new content outline. The Competency Committee will begin working with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Competency Committee Meetings

Competency Committee Workgroups have met three times during 2010 to develop the CPJE. Both Workgroups will meet together at their annual meeting in August to continue examination development as well as incorporate the new content outline and ensure implementation for examinations administered after April 1, 2011

Committee Discussion/Action

The committee took no action.

g. **FOR ACTION: Review and Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies**

Attachment 7

Background

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

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

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

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

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

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. Recently, the board modified its regulations for pharmacies that compound medication. Included in these 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, will take effect July 6, 2010. (The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.)

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

- 1. Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
- 2. Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law

and sound professional practice as established by nationally recognized professional or standard setting organizations.

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

4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).

5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.

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

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

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

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

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

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

Request

The following agencies are requesting approval by the board to serve as accreditation agencies approved by the board.

1. Accreditation Commission for Health Care, Inc. (ACHC)
2. Community Health Accreditation Program (CHAP)
3. Det Norske Veritas (DNV)

Committee Discussion/Action

The committee was advised of the outcome of staff review of the agencies, including concerns that surveys for each agency may not be adequately familiar with California law and indicated that the agencies may not be compliant with the new regulations that take effect July 6, 2010.

The committee also heard a presentation by Patrick Horine, representing Det Norske Veritas (DNV) Healthcare Inc. Mr. Horine provided an overview of their accreditation program and stated that the model standards used by DNV are consistent with California Pharmacy Law.

Public comment suggested that the board may also want to evaluate JCAHO using the same criteria.

The committee did not take action on this item.

Post Meeting Update

At the board's request, JCAHO submitted materials detailing how they satisfy the eight requirements listed above which was reviewed by staff. Additionally, board staff completed

inspections on two licensed pharmacies accredited by ACHC, CHAP and JACHO. DNV currently only accredits one California licensed pharmacy, which was also inspected. A spreadsheet documenting board staff findings is provided in **Attachment 7**.

During this Meeting

Supervising Inspector Janice Dang will provide a brief presentation to the board regarding her findings. DNV will also provide the board with a presentation. The application materials submitted by DNV are also in **Attachment 7** for board consideration. The board should be prepared to act on the application submitted by DNV.

ACHC and CHAP will be invited to the October 2010 Board Meeting, to present before the board. The board will consider their applications afterwards.

h. FOR INFORMATION: Update of the Licensing Committee's Strategic Plan for 2010-11

Attachment 8

Background

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

As part of the Organizational Development Committee Report scheduled for tomorrow, the board will be voting on the strategic plan in its entirety.

Committee Discussion/Action

The committee was provided with suggested additions to the strategic plan for consideration and discussion. The committee discussed the organization of the plan and requested clarification on the possible additions offered by staff.

Post Meeting Update

Board staff has revised their recommended additions to better define each task. The following tasks are being forwarded to the board for consideration and inclusion into the 2010-11 Strategic Plan and would be included under Objective 2.4 - - Implement at least 25 changes to improve licensing decisions by June 30, 2011.

20. Automate fingerprint background results with the Department of Justice
21. Evaluate pharmacy technician application process to identify areas for improvement
22. Implement Fingerprint Requirement for Pharmacist Renewal
23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership

Attachment 8 contains a copy of the committee's strategic plan for 2010-11.

i. **FOR INFORMATION: Minutes of the Meeting Held on June 16, 2010**

Attachment 9

A summary of the meeting held on June 16, 2010 is provided in **Attachment 9**.

j. **FOR INFORMATION: Licensing Statistics 2009/10**

Attachment 10

Attachment 10 includes the licensing statistics for 2009/10. Also provided are 5 year comparison charts detailing the growth the number of applications received, licenses issued and licensee population growth.

The board has experienced significant growth in its individual licensing classifications ranging from 4% to 67% in the number of applications received, 12% - 95% in the number of licenses issued and 13% to 36% in the total number of licensees.

In some classifications of site licensing the board has seen growth, such as with non-resident pharmacies, however in other areas, the workload fluctuates over the years. This is most apparent in the number of applications received from and the number of licenses issued to pharmacies. These spikes in workload are usually attributed to a chain store buyout.

k. **FOR INFORMATION: Fourth Quarterly Report on Licensing Committee Goals for 2009-10**

Attachment 11

Attachment 11 contains a copy of the board's licensing statistics and the fourth quarter's status of Licensing Committee Goals.

ATTACHMENT 1



UNIVERSITY OF
NEW ENGLAND

College of Pharmacy

RECEIVED BY CALIF.
BOARD OF PHARMACY

2010 APR 13 AM 8:43

Office of the Dean

Portland Campus
716 Stevens Avenue
Portland, ME 04103
(207) 221-4500 T
(207) 523-1917 F

April 6, 2010

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

Re: Recognition of University of New England College of Pharmacy

Dear Ms. Herold:

I would like to take this opportunity to petition the California State Board of Pharmacy to acknowledge our College of Pharmacy so that our students can be registered as interns in the state of California.

We are a new College of Pharmacy located in Portland, Maine. We were granted Pre-Candidate status by the Accreditation Council for Pharmacy Education (ACPE) at their June 2009 meeting, thus allowing us to enroll our Inaugural Class on September 9, 2009. We have two students that wish to return to California to complete their first Introductory Pharmacy Practice Experience (IPPE) from **May 17 – June 11, 2010**.

Our program is a four year professional program which allows students to complete the Doctorate of Pharmacy degree following the successful completion of two years of pre-pharmacy requirements. This program is comprised of the following pharmacy practice experiences:

Summer following Professional Year One

Introductory Pharmacy Practice Experience - Community: Students will practice as a pharmacy intern for four weeks (160 hours) in a community setting under the supervision of a licensed pharmacist. They will learn the distribution of a drug from the prescription received to the safe administration of the drug to the correct patient. Students will also learn operational aspects with all its related issues during the experiences.

Summer following Professional Year Two

Introductory Pharmacy Practice Experience - Institutional: Students will practice as a pharmacy intern for four weeks (160 hours) in an institutional setting under the supervision of a licensed pharmacist. They will learn the distribution of a drug from the order received to the safe administration of the drug to the correct patient. Students will also learn operational and clinical aspects with all its related issues during the experiences.

Professional Year Four

Advanced Pharmacy Practice Experiences: Starting at the completion of year three, the students will complete six rotations, each for six weeks. The required experiences will include Inpatient Acute Care, Ambulatory Care, Community and Institutional Pharmacy plus two APPE electives. Students will have the skills to integrate and apply their knowledge to real patient situations, as well as function as members of the healthcare team.

Listed below you will find the ACPE Detailed Accreditation History for the College, which was taken directly from their website (<http://www.acpe-accredit.org/deans/schools.asp>). As you can see, we are in the midst of the 2009-2010 Review Period for advancement to Candidate accreditation status. The ACPE site visit team will be on campus April 27, 28 and 29, 2010. The Board will announce their decision at the conclusion of their meeting in late June 2010. You may contact ACPE directly at (312) 664-3575 if further information is required.

Detailed Accreditation History

University of New England College of Pharmacy

716 Stevens Avenue

Portland, ME 40103

Douglas Kay, PhD

Dean

Tel: 207-221-4141

FAX: 207-221-1917

E-Mail: dkay@une.edu

Web Site: www.une.edu/pharmacy

Review Period	Review Type	Board Action	Status
2009-2010	Comprehensive - Advancement to candidate		
2008-2009	Comprehensive - Precandidate status	Granted	Precandidate
2008-2009	Initial Application		

We thank you and the Board of Pharmacy for your consideration of our time sensitive petition. Should you need further information or have any questions, please do not hesitate to contact my office at 207- 221-4141 or by email (dkay@une.edu).

With best regards,



Douglas Kay, PhD

Dean

College of Pharmacy

University of New England

ATTACHMENT 2

Modification of Intern Hours Proposal

Current Law: The California State Board of Pharmacy requires a total of 1500 Intern hours to be eligible for licensure. Of these, 600 can be in a setting that is "substantially related to the practice of pharmacy"; the remaining 900 hours must be in a pharmacy under the supervision of a pharmacist. The 600 hours is accepted as a part of the usual curriculum within a school or pharmacy (in California).

An affidavit is submitted by the Intern to the Board of Pharmacy, signed by an applicant, attesting to the fact that they have completed the required 1500 hours. While the Board may pursue an occasional audit, it is safe to say that the Board does not investigate the veracity of these affidavits.

Rationale for intern hour modification:

According to some students and faculty, there are two main reasons for exploring regulatory options:

- 1) Students are finding it more difficult to obtain the 900 required hours in a pharmacy. This may be due to budgetary constraints in chain or hospital practice and/or competition for intern sites (due to the addition of new pharmacy schools in California).
- 2) The practice of pharmacy has continued to expand beyond the four walls of a licensed pharmacy. While there should continue to be a requirement for intern experience within a licensed pharmacy, there is a need to recognize experiences in other established pharmacy practice environments.

UCSF Curriculum:

The UCSF Curriculum currently includes more than 1000 hours of advanced pharmacy practice experience that would meet the Board's criteria for hours that are "substantially related to the practice of Pharmacy". Under current law however, the students can only make use of 600 of these for licensure purposes. We assume the other California Schools of Pharmacy also meet or exceed this 1000 threshold.

Proposal:

We are proposing that the language dealing with intern hours be revised to allow 900 hours to be accrued within a school of pharmacy curriculum and a 600 hour requirement "in a pharmacy under the supervision of a pharmacist."

This modification would:

- 1) Diminish the student pharmacist's burden of finding licensed pharmacy sites for internship experiences.

- 2) Allow the schools greater flexibility in determining appropriate experiential requirements that are in line with contemporary practice; and
- 3) Retain a requirement for practice experience in a licensed pharmacy.

This proposal would have no impact on the Board of Pharmacy itself.

California Code of Regulations

1728. Requirements for Examination.

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

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

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

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

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

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

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

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

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

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

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

Authority cited: Sections 851, and 4005, Business and Professions Code. Reference: Sections 144, 851, and 4200, Business and Professions Code.

Intern Hours Chronology

March 2006

Licensing Committee heard a presentation from pharmacy students requesting that the board amend the intern hour requirement to increase the number of pharmacy-related experience earned outside a pharmacy to 1,000 hours. Under this proposal, an intern would have only 500 hours of experience in a pharmacy. The committee expressed concern that a minimum of 500 hours in the pharmacy setting is not sufficient to ensure adequate public safety and the experience necessary to perform the duties of a pharmacist.

December 2006

Licensing Committee heard a second presentation from pharmacy students which highlighted the additional pharmacy-related areas an intern could pursue if the intern hours experience requirement were more flexible. The committee concluded that it was premature to move forward with this proposal at that time.

During the same meeting, the committee was advised on a project initiated by the California Schools of Pharmacy to review basic intern experience earned by students. This project would assess the competencies that should be achieved by the end of the introductory pharmacy experience, referred to as IPPEs. The committee recommended that the board participate in this project. Board Member Ravnar was the designated board representative for the project.

March 2007

Licensing committee was provided with the competencies developed by schools of pharmacy along with a request that the board affirm its agreement with the document.

October 2007

Through a written statement to California schools of pharmacy the board recognized the competencies developed by the schools. "The California Board of Pharmacy recognizes these competencies as appropriate competencies for a California licensed pharmacist to possess, and the board strongly supports the need for interns to develop and expand their competency in these areas as among the core responsibilities of pharmacists."

June 2008

Licensing Committee revisited the request to alter the intern hour requirements in light of the completion and recognition by the board of the competency statements developed by the schools of pharmacy. After much discussion and deliberation the committee tabled the discussion.

December 2008

Licensing Committee discussed a written request from a Loma Linda student suggesting that the intern hours requirement allow more flexibility in practice sites in which intern hours can be earned, such as ambulatory care. After discussion and public comment, the committee did not take action on this item.

June 2009

Licensing Committee discussed how the board would confirm compliance of intern hours worked – the committee did not discuss changing the current intern hour requirements specified in law. However, following a subsequent discussion with counsel, it was determined that the solution offered by the committee did not comply with legal requirements detailed in pharmacy law.

December 2009

Licensing Committee discussed intern hours reporting requirements to clarify the requirements detailed in pharmacy law. The board released a statement to all schools of pharmacy, and placed the information on the board's Web site.

ATTACHMENT 3

**Continuing Education Audit Monthly Statistics
September 2009- May 2010
FY 09/10**

September 2009

	#	%
RPhs Audited	25	
Cite & Fine	1	4%
Inactive Status	0	0%
Passed	24	96%
Failed	1	4%

Reason(s): Failed to respond 1

October 2009

	#	%
RPhs Audited	24	
Cite & Fine	3	13%
Inactive Status	0	0%
Passed	21	88%
Failed	3	12%

Reason(s): Short CE- not compliant still 2
Failed to respond 1

November 2009

	#	%
RPhs Audited	27	
Cite & Fine	4	15%
Inactive Status	1	4%
Passed	23	85%
Failed	4	15%

Reason(s): Short CE- now compliant 3
Failed to respond 1

December 2009

	#	%
RPhs Audited	24	
Cite & Fine	2	8%
Inactive Status	1	4%
Passed	21	88%
Failed	3	12%

Reason(s): Short CE- now compliant 2
Failed to respond 1

January 2010

	#	%
RPhs Audited	27	
Cite & Fine	3	11%
Inactive Status	2	7%
Passed	24	89%
Failed	3	11%

Reason(s): Short CE- now compliant 1
Failed to respond 2

February 2010

	#	%
RPhs Audited	23	
Cite & Fine	3	13%
Inactive Status	0	0%
Passed	20	87%
Failed	3	13%

Reason(s): Short CE- now compliant 2
Short CE- not compliant still 1

March 2010 & April 2010

	#	%
RPhs Audited	50	
Cite & Fine	11	22%
Inactive Status	1	2%
Passed	37	74%
Failed	13	26%

Reason(s): Short CE- now compliant 11
 Short CE- not compliant still 2

May 2010

	#	%
RPhs Audited	26	
Cite & Fine	6	23%
Inactive Status	1	4%
Passed	20	77%
Failed	6	23%

Reason(s): Short CE- now compliant 4
 Short CE- not compliant still 1
 Failed to respond 1

June 2010

	#	%
RPhs Audited	22	
Cite & Fine	1	5%
Inactive Status	0	0%
Passed	21	95%
Failed	1	5%

Reason(s): Short CE- now compliant 1

**Continuing Education Audit Final Statistics
September 2009- May 2010
FY 09/10**

Final Statistics

	#	%
Total RPhs Audited	248	
Cite & Fine	34	14%
Inactive Status	6	2%
Total Passed	211	85%
Total Failed	37	15%

Fail Explanations

	#	%
Short CE- now compliant	24	65%
Short CE- not compliant still	6	16%
Failed to respond	7	19%

Total: 37 100%

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.

ATTACHMENT 4



National Practitioner Data Bank Healthcare Integrity and Protection Data Bank



FACT SHEET ON SELF-QUERYING

Practitioner, Provider, and Supplier Self-Query

A self-query is a request by a practitioner, provider, or supplier for information about himself, herself, or his or her organization contained in the National Practitioner Data Bank (NPDB) and/or the Healthcare Integrity and Protection Data Bank (HIPDB).

Practitioners, providers, and suppliers may self-query the Data Banks at any time. To initiate a self-query, go to the Data Banks Web site, at www.npdb-hipdb.hrsa.gov. **All self-query applications must be submitted through the NPDB-HIPDB Web site. After initiating the self-query on-line, the practitioner must print and sign the form in the presence of a Notary Public and then mail the signed, notarized form to the Data Banks.** Self-queriers who do not have access to the Internet may call the NPDB-HIPDB Customer Service Center for assistance at 1-800-767-6732 (TDD 703-802-9395).

Subject Report Information in the Data Banks

The NPDB and the HIPDB are committed to maintaining accurate information and ensuring that health care practitioners, providers, and suppliers are informed when medical malpractice payments, adverse actions, and judgments or convictions are reported concerning them. When the Data Banks receive a report, the information is processed by the NPDB-HIPDB exactly as submitted by the reporting entity. Reporting entities are responsible for the accuracy of the information they report to the Data Banks.

When the Data Banks process a report, a *Report Verification Document* is sent to the reporting entity, and a *Notification of a Report in the Data Bank(s)* is sent to the subject. The subject should review the report for accuracy, including such information as current address and place of employment.

Subjects may not submit changes to reports. If report information is inaccurate, the subject must contact the reporting entity to request that it file a Correction, Revision to Action, or Void. The Data Banks are prohibited by law from modifying information submitted in reports. For information on submitting a statement or a dispute to a report, see the *Fact Sheet on the Dispute Process*.

Self-Querying on the Internet

The NPDB-HIPDB employs the latest technology, along with various implementation measures, to provide a secure environment for querying, reporting, data storage, and retrieval. Security features include firewall protection from unauthorized access and encryption of transmitted data to prevent unauthorized use.

Self-queriers complete and transmit their self-queries to the NPDB-HIPDB on-line; however, a self-query is not officially submitted until a signed and notarized paper copy is received by the Data Banks. A formatted copy of the self-query is generated immediately after electronic transmission. To complete the self-query process, self-queriers must print the formatted copy, sign and date it in the presence of a notary public, and mail the notarized self-query to the address specified. After processing the self-query, the Data Banks send an e-mail alerting the practitioner that the self-query response is available for on-line viewing. In addition to the electronic response, you will receive a paper copy (or copies), if you have elected to do so.

Self-Query Fees

Individual and organization self-query requests are automatically sent to both the NPDB and the HIPDB for a total charge of \$16.00. The fee consists of an NPDB charge of \$8.00 per self-query and a HIPDB charge of \$8.00 per self-query. **Note:** One mailed copy is included in the self-query processing fee. Each additional paper copy of your self-query response will be assessed a fee by each Data Bank under which the self-query is processed.

All self-query fees must be paid by credit card (VISA, MasterCard, Discover, or American Express). Personal checks and cash are not accepted. Credit card information may be provided either on-line or written on the formatted copy that is printed for notarization. The credit card will not be charged until the NPDB-HIPDB receives and processes the notarized self-query. A notarized self-query lacking credit card information will be rejected.

Self-Query Mailed Responses

The NPDB-HIPDB does not accept stamped, photocopied, or faxed signatures, and faxed self-queries cannot be accepted. Previously processed self-queries are also not accepted. You may reduce transit time by submitting self-queries via U.S. Postal Service Express mail to the address at the top of this fact sheet, or by returning your self-query through another overnight delivery carrier to the following street address:

NPDB-HIPDB
4094 Majestic Lane, PMB-332
Fairfax, Virginia 22033

Please do not enclose pre-paid, self-addressed envelopes for overnight return mail delivery with your formatted self-query application.

Self-query notification is sent to practitioners via an e-mail alerting them that their self-query results are available for viewing and printing on-line. During the self-query process, practitioners create a personal response password enabling them to log in to the Self-Query Service and view the self-query response.

In addition to the electronic response, practitioners will still receive one paper copy by mail for the \$16.00 self-query processing fee (unless they elect not to receive a mailed copy). Practitioners and organizations can also request additional sealed copies of their self-query response. Each additional copy has a separate processing fee of \$16.00. Self-query responses are mailed separately to the address specified in the self-query submission.

Self-Query Notarization

All self-queries must be notarized, and all fields in the notarization section must be completed. The NPDB-HIPDB will reject any self-query received without notarization or with an incomplete notarization. The NPDB-HIPDB requires notarization of the formatted copy of the self-query to protect the privacy of sensitive and confidential information requested by practitioners, providers, and suppliers. By appearing before a notary and having the notary sign and date the form, the NPDB-HIPDB is reasonably assured that the individual submitting the self-query has requested the information on behalf of himself, herself, or his or her organization.

To successfully process a self-query, both the self-querier and the notary public must sign and date the form. The notary must also provide the date that his or her commission expires and affix his or her seal. If the notary public does not have a stamp or seal, he or she must provide other proof of office (e.g., a copy of a notary certificate). The only lawful date on a notarial certificate is the date the signer actually appeared, according to *12 Steps to a Flawless Notarization* published by the National Notary Association.

Self-Query Status

On the *Self-Query Service Sign-In* screen, enter the Self-Query Tracking #/DCN and then click **Continue**. Self-queriers enter a password to check the status of a self-query, following the on-screen instructions. The *Self-Query Status* screen will display status information for the indicated self-query.

NPDB-HIPDB Assistance

For additional information, visit the NPDB-HIPDB Web site at www.npdb-hipdb.hrsa.gov. If you need assistance, contact the NPDB-HIPDB Customer Service Center by e-mail at help@npdb-hipdb.hrsa.gov or by phone at 1-800-767-6732 (TDD 703-802-9395). Information Specialists are available to speak with you weekdays from 8:30 a.m. to 6:00 p.m. (5:30 p.m. on Fridays) Eastern Time. The NPDB-HIPDB Customer Service Center is closed on all Federal holidays.

OCCUPATION/FIELD OF LICENSURENational Practitioner Data Bank
Healthcare Integrity and Protection Data Bank**Entity: CALIFORNIA STATE BOARD OF PHARMACY (SACRAMENTO, CA)**

Please select the code that best describes the subject's occupational activities or licensure category associated with the adverse action being reported.

- Physician**
- Nurse - Advanced, Registered, Vocational or Practical**
- Nurse Aide, Home Health Aide And Other Aide**
- Dental Service Practitioner**
- Chiropractor**
- Counselor**
- Dietician/Nutritionist**
- Emergency Medical Technician (EMT)**
- Eye and Vision Service Practitioner**
- Pharmacy Service Practitioner**
 - Pharmacist (050)
 - Pharmacy Intern (055)
 - Pharmacist, Nuclear (060)
 - Pharmacy Assistant (070)
 - Pharmacy Technician (075)
- Physician Assistant**
- Podiatric Service Practitioner**
- Psychologist/Psychological Assistant**
- Rehabilitative, Respiratory and Restorative Service Practitioner**
- Social Worker**
- Speech, Language and Hearing Service Practitioner**
- Technologist/Technician**
- Other Health Care Practitioner**
- Health Care Facility Administrator**
- Other Occupation**

[Continue](#)[Return to Options](#)[Log Out](#)

ATTACHMENT 5

Disaster Response Policy Statement

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal).

The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

¹Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

²See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Business and Professions Code Section 4062

4062. Furnishing Dangerous Drugs During Emergency; Mobile Pharmacy

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared emergency area or affected areas.

(6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

ATTACHMENT 6

**California State Board of Pharmacy
CPJE Statistics 10/1/09 – 3/31/10**

The charts below display data for all candidates who took the CPJE examination between 10/1/09 – 3/31/10, inclusive.

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

Overall Pass Rates

CPJE

	Frequency	Percent
Valid F	198	27.9
P	511	72.1
Total	709	100.0

NAPLEX

	Frequency	Percent
Valid F	27	3.9
P	662	96.1
Total	689	100.0

Location of School

CPJE

			JPE		JPE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	31	126	157	3	153	156
		% within PF	19.7	80.3	100	1.9	98.1	100
	Other US	Count	106	271	377	9	351	360
		% within PF	28.1	71.9	100	2.5	97.5	100
	Foreign	Count	61	113	174	15	157	172
		% within PF	35.1	64.9	100	8.7	91.3	100
	Unclassified	Count	0	1	1	0	1	1
		% within PF	0	100	100	0	100	100
Total		Count	198	511	709	27	662	689
		% within PF	27.9	72.1	100	3.9	96.1	100

Gender

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	133	326	459	23	419	442
		% within PF	29.0	71.0	100	5.2	94.8	100
	M	Count	65	185	250	4	243	247
		% within PF	26.0	74.0	100	1.6	98.4	100
Total		Count	198	511	709	27	662	689
		% within PF	27.9	72.1	100	3.9	96.1	100

Degree

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy	Count	70	127	197	19	175	194
		% within PF	35.5	64.5	100	9.8	90.2	100
	Pharm D.	Count	128	384	512	8	487	495
		% within PF	25.0	75.0	100	1.6	98.4	100
Total		Count	198	511	709	27	662	689
		% within PF	27.9	72.1	100	3.9	96.1	100

California Schools

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	4	14	18	0	17	17
		% within PF	22.2	77.8	100	0	100	100
	UOP	Count	10	39	49	0	49	49
		% within PF	20.4	79.6	100	0	100	100
	USC	Count	6	18	24	0	24	24
		% within PF	25.0	75.0	100	0	100	100
	Western	Count	5	21	26	1	25	26
		% within PF	19.2	80.8	100	3.8	96.2	100
	Loma Linda	Count	0	10	10	0	10	10
		% within PF	0	100	100	0	100	100
	UCSD	Count	0	8	8	0	8	8
		% within PF	0	100	100	0	100	100
	Touro U	Count	6	16	22	2	20	22
		% within PF	27.3	72.7	100	9.1	90.9	100
Total		Count	31	126	157	3	153	156
		% within PF	19.7	80.3	100	1.9	98.1	100

US Schools of Pharmacy

	JPE pass fail status		Total
	F	P	
U of AZ	0	2	2
U of AR	0	2	2
UCSF	4	14	18
U of Pacific	10	39	49
USC	6	18	24
U of CO	1	4	5
U of Conn	0	2	2
Howard DC	0	3	3
FL A&M	0	1	1
U of FL	2	11	13
Mercer	1	2	3
U of GA	1	0	1
Idaho SU	2	3	5
U of IL Chi	4	5	9
Purdue	1	3	4
Drake	3	1	4
U of IA	0	4	4
U of KS	1	0	1
U of KY	0	1	1
NE LA U	0	3	3
Xavier	2	6	8
U of MD	3	8	11
MA Col Pharm	13	24	37
NE-MA	3	6	9
Ferris	0	3	3
U of MI	1	6	7
Wayne SU	0	1	1
U of MN	1	1	2
St. Louis Col of PH	1	4	5
UMKC	1	0	1
U of MT	2	1	3
Creighton	4	5	9
U of NE	0	2	2
Rutgers	3	8	11
U of NM	2	4	6
Western	5	21	26
Midwstern U	1	6	7
Chicago			
A&M Schwartz	1	4	5
St. Johns	1	0	1
SUNY-Buff	3	3	6
Union U	0	3	3
UNC	0	2	2

	JPE pass fail status		Total
	F	P	
OH Nrthn U	0	1	1
OH State U	2	4	6
U of Cinn	2	1	3
U of Toledo	0	3	3
U of OK	2	2	4
OR State U	0	2	2
Duquesne	0	2	2
Phi C of Pharm	3	10	13
Temple	2	4	6
U of Pitt	0	1	1
U of RI	1	1	2
U of SC	1	1	2
U of Hous	2	6	8
U of TX	1	1	2
U of UT	1	0	1
Med C of VA	2	1	3
U of WA	0	3	3
WA State U	5	1	6
WV U	0	2	2
U of WI-Mad	0	4	4
U of WY	2	2	4
Nova Southeastern	3	8	11
Wilkes University	0	1	1
Texas Tech	0	1	1
Bernard J Dunn	2	3	5
Midwestern AZ	1	8	9
Nevada College of Pharm	10	37	47
Loma Linda U	0	10	10
UCSD	0	8	8
MA School of Pharm - Worcester	2	7	9
Palm Beach Atlantic University	1	0	1
Lake Erie Col	1	2	3
Touro U	6	16	22
U of Appalachia	0	2	2
South U School of Pharm	1	0	1
Pac U of Or	1	6	7
Unclassified	0	1	1
Other/FG	61	113	174
Total	198	511	709

Country

	JPE pass fail status		Total
	F	P	
Bulgaria	2	0	2
Brazil	1	0	1
Canada	1	7	8
China	2	3	5
Egypt	6	17	23
Fiji	0	1	1
United Kingdom	0	2	2
India	15	26	41
Iraq	1	0	1
Iran	0	4	4
Italy	1	0	1
Jordan	1	2	3
S. Korea	2	6	8
Lebanon	1	0	1
Morocco	1	0	1
Moldova	0	1	1
Malta	0	1	1
Mexico	1	1	2
Nigeria/New Guinea	2	4	6
Philippines	18	22	40
Russia	0	1	1
Sweden	1	1	2
Suriname	0	1	1
Syria	0	1	1
Taiwan	1	1	2
Ukranian	1	2	3
UK	0	1	1
USA	138	402	540
South Africa	2	4	6
	198	511	709

OVERALL PASS RATES
5-Year Comparison by Exam Type

CPJE

	4/05-9/05		10/05-3/06		4/06-9/06		10/06-3/07		4/07-8/07		09/07-03/08		04/08-09/08		10/08-4/09		4/09-9/09		10/09-3/10	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pass	861	77.5	494	80.3	796	80.2	420	69.9	845	85.5	553	73	979	81.6	543	75.2	953	78.3	511	72.1
Total	1111	100	615	100	992	100	601	100	988	100	758	100	1200	100	722	100	1217	100	709	100

NAPLEX

	4/05-9/05		10/05-3/06		4/06-9/06		10/06-3/07		4/07-8/07		09/07-03/08		04/08-09/08		10/08-4/09		4/09-9/09		10/09-3/10	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pass	1018	95.9	499	91.1	905	94.5	477	90.7	918	95.7	688	94.5	1112	97.6	661	96.9	1140	97.8	662	96.1
Total	1061	100	548	100	958	100	526	100	959	100	728	100	1139	100	682	100	1166	100	689	100

ATTACHMENT 7

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. •Premier Infusion Care inspected 6/10/2010. •Findings: 1)corrections issued for justification for chosen expiration dates; 2) when monitoring personal performance, equipment and facilities, if testing “fails” document what corrective actions taken; 3)document annual competencies of personnel; 4) disinfect weekly surfaces and other hard surfaces in designated area like floors, walls, ceilings, shelves, tables, stools; 5) four separate refrigerators with only 1-being monitored; 6) completion of new self assessment form. 	<ul style="list-style-type: none"> •Hoag Medical Center inspected 6/14/2010 •Findings: 1) labeling to include prescriber as required by BPC4076; 2) statement product is compounded per CCR 1735.4(b); 3) exterior workbench surfaces and other hard surfaces in the designated cleanroom disinfected weekly and after any unanticipated event; 4) requirement of completion of new self assessment form. 	<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>
<p>7. Length of time accrediting agency has been operating as an accrediting agency.</p>	<p>ACHC is an independent, private, not for profit corporation established in 1986.</p>	<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. 	<p>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.</p>
<p>8. Ability to accredit out-of-state pharmacies.</p>	<p>ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.</p>	<p>As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.</p>	<ul style="list-style-type: none"> •Refer to #7 	<p>The Joint Commission can and does accredit pharmacies throughout the United States.</p>
<p>9. Annual submission of list of accredited board of licensed facilities.</p>	<p>List received.</p>	<ul style="list-style-type: none"> •CHAP has 6 currently accredited pharmacy sites in CA. •Current list submitted 6/4/2010. 	<p>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.</p>	<p>List received. Also an internet search is available on The Joint Commission website to verify accreditation.</p>

DNV Standards Comparison to California Pharmacy Laws
(Refer to Criteria #2)

Requirments	California Law	DNV Standard
Compounding in Licensed Pharmacies	CCR 1735	Interpretive guidelines for MS.8 Sterile Compounding (Optional)
Compounding definitions: integrity, potency, quality, strength	CCR 1735.1	Interpretive guidelines for MS.8 Sterile Compounding (Optional)
Compounding limitations and requirements	CCR 1735.2	SR1, SR2, SR3, SR4, SR5, SR7, SR8, SR10
Records of Compounded Drug Products	CCR 1735.3	SR11, SR12, SR13
Labeling of Compounded Drug Products	CCR 1735.4	SR14, SR15, SR16,
Compounding Policies and Procedures	CCR 1735.5	SR17
Compounding facilities and equipment	CCR 1735.6	SR18
Training of Compounding Staff	CCR 1735.7	SR19, SR20
Compounding Quality Assurance	CCR 1735.8	SR21
Sterile Injectable Compounding; Compounding Area	CCR 1751	SR22
Compounding sterile injectable product from one or more nonsterile ingredients shall comply with 4127.7	CCR 1751(c)	SR23
Sterile injectable recordkeeping requirements	CCR 1751.1	SR24
Sterile injectable labeling requirements	CCR 1751.2	SR25
Sterile injectable policies and procedures	CCR 1751.3	SR26, SR27
Facility and Equipment Standards for Sterile Injectable Compounding	CCR 1751.4	SR28, SR29
Sterile injectable compounding attire	CCR 1751.5	SR29, SR30
Training of sterile injectable compounding	CCR 1751.6	SR31, SR32
Sterile injectable compounding	CCR 1751.7	SR33, SR34, SR34(f)(1), SR34(f)(2)
Sterile injectable compounding	CCR1751.8	Need to add.

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.

New -- Det Norske
Veritas (DNV)

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
 - SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
 - SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.
- SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
 - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
 - *All non-controlled substances are to be locked when a patient care area is not staffed.*
 - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices. There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
 - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
 - *Labeling of medications*
 - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
 - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;*
- *Availability of up-to-date medication information;*
- *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;*
- *Avoidance of dangerous abbreviations;*
- *Alert systems for look-like and sound-alike drug names;*
- *Use of facility approved pre-printed order sheets whenever possible.*
- *That orders to "resume previous orders" are prohibited;*
- *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- *The preparation, distribution, administration and proper disposal of hazardous medications;*
- *Drug recalls;*
- *That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- *Identification of when weight-based dosing for pediatric populations is required;*
- *Other relevant performance improvement activities*

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- *Verify the process for ensuring correct patient identification*
- *Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.*
- *Review the process followed when medications are not given on time and what action(s) are taken*

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- *name and strength of the drug;*

- lot and control number equivalent; and,
- expiration date.

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- Patient's full name;
- the prescriber's name;
- strength and quantity of the drug dispensed; and,
- appropriate accessory and cautionary statements are included as well as the expiration date .

Review and verify that medications provided in floor stock include:

- the name and strength of the drug;
- lot and control number of equivalent; and
- expiration date.

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals .

Review the transfusions and intravenous medications practices

- Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices
 - Review the course content to ensure that the following information is included at a minimum:
 - Fluid and electrolyte balance
 - Blood components
 - Venipuncture techniques, returned demonstration and supervised practice

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

- SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
- SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;
- Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;
- Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,
- Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.
 - SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants);
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Indication for use when appropriate;
- Specific instructions for use; and
- Name of prescriber.

Hospitals should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal/telephone orders;
- Provide a mechanism to ensure validity/authenticity of the prescriber;
- List the elements required for inclusion in a complete verbal/telephone order ;
- Describe situations in when verbal/telephone orders may be used;
- List and define the individuals who may send and receive verbal/telephone orders; and,
- Provide guidelines for clear and effective communication of verbal/telephone orders.

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.
- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in this area shall be segregated and unavailable.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
- SR.5a potential drug-drug interactions;
 - SR.5b potential allergies or cross sensitivities;
 - SR.5c proper dose ranges; and,
 - SR.5d proper indications for administration.
- SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- *The practitioner caring for the patient must determine the urgency of administration;*
- *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
- *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*
- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
 - *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
 - *All high-risk medications in this area shall be segregated and unavailable;*
 - *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
 - *potential drug-drug interactions;*
 - *potential allergies or cross sensitivities;*
 - *proper dose ranges, and*
 - *proper indications for administration.*
- *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
- *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.
- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

- SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.
- SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:
- SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and
 - SR.3b is reasonable considering the intended use of the compounded medication; and
 - SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:
- SR.4a Active ingredients to be used.
 - SR.4b Inactive ingredients to be used.
 - SR.4c Process and/or procedure used for preparation of the drug product.
 - SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
 - SR.4e Post-compounding process or procedures required, as applicable.
 - SR.4f Dates of expiration/use by dates as required.
- Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.
- SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.
- SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.
- SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.
- SR.11 For each compounded drug product, the pharmacy records shall include:
- SR.11a The master formula record.
 - SR.11b The date the drug product was compounded.
 - SR.11c The name of the pharmacy personnel who compounded the drug product.

- SR.11d The name of the pharmacist reviewing the final drug product.
- SR.11e The quantity of each component used in compounding the drug product.
- SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
- SR.11g The equipment used in compounding the drug product.
- SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
- SR.11i The expiration date of the final compounded drug product.
- SR.11j The quantity or amount of drug product compounded.

- SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.
- SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).
- SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.
- SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.
- SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:
 - SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.
 - SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.
 - SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
- SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

- SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.
- SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.
- SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .
- SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.
- SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.
- SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.
- SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.
- SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.
- SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.
- SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:
- SR.22a Clean Room and Work Station Requirements.
- SR.22b Construction of walls, ceilings and floors.
- SR.22c Maintain appropriate ventilation of the preparation area.
- SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.
- SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.
- SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.

SR.24a(2) Monitoring of refrigerator and freezer temperatures.

SR.24a(3) Certification of the sterile compounding environment.

SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).

SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

SR.25b Name and concentrations of ingredients contained in the sterile injectable product.

SR.25c Instructions for storage and handling

SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.

SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

SR.26c Equipment and supplies used.

SR.26d Training of staff regarding the preparation of sterile injectable products.

SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).

SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation

SR.27b Storage and handling of products and supplies.

SR.27c Storage and delivery of final products.

SR.27d Process validation of processes.

SR.27e Personnel access and movement of materials into and near the controlled area.

SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

- SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
- SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
- SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- SR.27j Sterilization.
- SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

- SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:
 - SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.
 - SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.
 - SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.
 - SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.
- SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.
- SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:
 - SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
 - SR.30b Clean room attire must be donned and removed outside the designated area.
 - SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).
- SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

- SR.32a(1) Use of aseptic preparation technique and procedures.
- SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
- SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
- SR.32a(4) Documentation of Sterile product compounding.
- SR.32a(5) Appropriate use of sterilization techniques.
- SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- SR.32a(7) Selection of containers, equipment, and closure system.
- SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall be documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.

SR.34b Storage of compounded sterile injectable products in the Pharmacy

SR.34c Periodic documentation of refrigerator temperatures.

SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.

SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.

SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- Altering the dosage form or delivery system of a drug
- Altering the strength of a drug
- Combining components or active ingredients
- Combining components or active ingredients
- Preparing a drug product from chemicals or bulk drug substances

“Compounding” does not include:

- does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product:

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

ISO Class 7 guidelines are met when particulate contamination is measured at “not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room).”

ISO Class 8 guidelines are met when particulate contamination is measured at “not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area).”

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- compounding of drugs*
- compounding sterile injectable products from one or more non-sterile ingredients*
- preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
- SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
- SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.
- SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
 - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
 - *All non-controlled substances are to be locked when a patient care area is not staffed.*
 - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices. There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
 - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
 - *Labeling of medications*
 - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
 - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Avoidance of dangerous abbreviations;
- Alert systems for look-like and sound-alike drug names;
- Use of facility approved pre-printed order sheets whenever possible.
- That orders to "resume previous orders" are prohibited;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Drug recalls;
- That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- Identification of when weight-based dosing for pediatric populations is required;
- Other relevant performance improvement activities

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- Verify the process for ensuring correct patient identification
- Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.
- Review the process followed when medications are not given on time and what action(s) are taken

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- name and strength of the drug;

- lot and control number equivalent; and,
- expiration date.

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- Patient's full name;
- the prescriber's name;
- strength and quantity of the drug dispensed; and,
- appropriate accessory and cautionary statements are included as well as the expiration date .

Review and verify that medications provided in floor stock include:

- the name and strength of the drug;
- lot and control number of equivalent; and
- expiration date.

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals

Review the transfusions and intravenous medications practices

- Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices
 - Review the course content to ensure that the following information is included at a minimum:
 - Fluid and electrolyte balance
 - Blood components
 - Venipuncture techniques, returned demonstration and supervised practice

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

- SR.1 *Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.*
- SR.2 *Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.*

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- *Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*
- *Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*
- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*
- *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.
 - SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants);
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Indication for use when appropriate;
- Specific instructions for use; and
- Name of prescriber.

Hospitals should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal/telephone orders;
- Provide a mechanism to ensure validity/authenticity of the prescriber;
- List the elements required for inclusion in a complete verbal/telephone order ;
- Describe situations in when verbal/telephone orders may be used;
- List and define the individuals who may send and receive verbal/telephone orders; and,
- Provide guidelines for clear and effective communication of verbal/telephone orders.

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.
- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in this area shall be segregated and unavailable.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - SR.5a potential drug-drug interactions;
 - SR.5b potential allergies or cross sensitivities;
 - SR.5c proper dose ranges; and,
 - SR.5d proper indications for administration.
- SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- *The practitioner caring for the patient must determine the urgency of administration;*
- *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
- *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*
- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
 - *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
 - *All high-risk medications in this area shall be segregated and unavailable;*
 - *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
 - *potential drug-drug interactions;*
 - *potential allergies or cross sensitivities;*
 - *proper dose ranges, and*
 - *proper indications for administration.*
- *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
- *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.
- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

- SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.
- SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:
- SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and
 - SR.3b is reasonable considering the intended use of the compounded medication; and
 - SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:
- SR.4a Active ingredients to be used.
 - SR.4b Inactive ingredients to be used.
 - SR.4c Process and/or procedure used for preparation of the drug product.
 - SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
 - SR.4e Post-compounding process or procedures required, as applicable.
 - SR.4f Dates of expiration/use by dates as required.
- Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.
- SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.
- SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.
- SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.
- SR.11 For each compounded drug product, the pharmacy records shall include:
- SR.11a The master formula record.
 - SR.11b The date the drug product was compounded.
 - SR.11c The name of the pharmacy personnel who compounded the drug product.

- SR.11d The name of the pharmacist reviewing the final drug product.
- SR.11e The quantity of each component used in compounding the drug product.
- SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
- SR.11g The equipment used in compounding the drug product.
- SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
- SR.11i The expiration date of the final compounded drug product.
- SR.11j The quantity or amount of drug product compounded.

- SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.
- SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).
- SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.
- SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.
- SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:
 - SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.
 - SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.
 - SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
- SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

- SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.
- SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.
- SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .
- SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.
- SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.
- SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.
- SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.
- SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.
- SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.
- SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:
- SR.22a Clean Room and Work Station Requirements.
- SR.22b Construction of walls, ceilings and floors.
- SR.22c Maintain appropriate ventilation of the preparation area.
- SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.
- SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.
- SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.

SR.24a(2) Monitoring of refrigerator and freezer temperatures.

SR.24a(3) Certification of the sterile compounding environment.

SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).

SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

SR.25b Name and concentrations of ingredients contained in the sterile injectable product.

SR.25c Instructions for storage and handling

SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.

SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

SR.26c Equipment and supplies used.

SR.26d Training of staff regarding the preparation of sterile injectable products.

SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).

SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation

SR.27b Storage and handling of products and supplies.

SR.27c Storage and delivery of final products.

SR.27d Process validation of processes.

SR.27e Personnel access and movement of materials into and near the controlled area.

SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

- SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
- SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
- SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- SR.27j Sterilization.
- SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

- SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:
 - SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.
 - SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.
 - SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.
 - SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.
- SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.
- SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:
 - SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
 - SR.30b Clean room attire must be donned and removed outside the designated area.
 - SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).
- SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

- SR.32a(1) Use of aseptic preparation technique and procedures.
- SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
- SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
- SR.32a(4) Documentation of Sterile product compounding.
- SR.32a(5) Appropriate use of sterilization techniques.
- SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- SR.32a(7) Selection of containers, equipment, and closure system.
- SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.

SR.34b Storage of compounded sterile injectable products in the Pharmacy

SR.34c Periodic documentation of refrigerator temperatures.

SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.

SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.

SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- Altering the dosage form or delivery system of a drug
- Altering the strength of a drug
- Combining components or active ingredients
- Combining components or active ingredients
- Preparing a drug product from chemicals or bulk drug substances

“Compounding” does not include:

- does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product.

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

ISO Class 7 guidelines are met when particulate contamination is measured at “not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room).”

ISO Class 8 guidelines are met when particulate contamination is measured at “not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area).”

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- compounding of drugs*
- compounding sterile injectable products from one or more non-sterile ingredients*
- preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

1735.2 (a)	Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
1735.2 (b)	A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
1735.2 (c)	Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
1735.2 (c)1	is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
1735.3 (c)2	is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
1735.2 (c)3	for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
1735.2 (d)	A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
1735.2 (d)1	Active ingredients to be used.
1735.2 (d)2	Inactive ingredients to be used.
1735.2 (d)3	Process and/or procedure used to prepare the drug.

MM.8 SR.1
MM.8 SR.2
MM.8 SR.3
MM.8 SR.3a
MM.8 SR.3b
MM.8 SR.3c
MM.8 SR.4
MM.8 SR.4a
MM.8 SR.4b
MM.8 SR.4c

1735.2 (d)4	Quality reviews required at each step in preparation of the drug.
1735.2 (d)5	Post-compounding process or procedures required, if any.
1735.2 (d)6	Expiration dating requirements.
1735.2 (e)	Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
1735.2 (f)	The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
1735.2 (g)	All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
1735.2 (h)	Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
1735.2 (i)	The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

MM.8 SR.4d
MM.8 SR.4e
MM.8 SR.4f
MM.8 SR.11
MM.8 SR.5
MM.8 SR.7
MM.8 SR.8
MM.8 SR.5

	Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
1735.2 (j)	
1735.3 (a)	For each compounded drug product, the pharmacy records shall include:
1735.3 (a)1	The master formula record.
1735.3 (a)2	The date the drug product was compounded.
1735.3 (a)3	The identity of the pharmacy personnel who compounded the drug product.
1735.3 (a)4	The identity of the pharmacist reviewing the final drug product.
1735.3 (a)5	The quantity of each component used in compounding the drug product.
1735.3 (a)6	The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
1735.3 (a)7	The equipment used in compounding the drug product.

	MM.8 SR.10
	MM.8 SR.11
	MM.8 SR.11a
	MM.8 SR.11b
	MM.8 SR.11c
	MM.8 SR.11d
	MM.8 SR.11e
	MM.8 SR.11f
	MM.8 SR.11g

1735.3 (a)8	A pharmacy assigned reference or lot number for the compounded drug product.
1735.3 (a)9	The expiration date of the final compounded drug product.
1735.3 (a)10	The quantity or amount of drug product compounded.
1735.3 (b)	Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
1735.3 (c)	Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.
1735.3 (d)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.
1735.4 (a)	In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
1735.4 (b)	A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
1735.4 (c)	Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

MM.8 SR.11h
MM.8 SR.11i
MM.8 SR.11j
MM.8 SR.12
MM.8 SR.13
MM.8 SR.12
MM.8 SR.14
MM.8 SR.15
MM.8 SR.16

1735.5 (a)	Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
1735.5 (b)	The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
1735.5 (c)	The policy and procedure manual shall include the following:
1735.5 (c)1	Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
1735.5 (c)2	Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
1735.5 (c)3	The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
1735.5 (c)4	Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
1735.5 (c)5	Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
1735.6 (a)	Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
1735.6 (b)	Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

MM.8 SR.17
MM.8 SR.17
MM.8 SR.17
MM.8 SR.17a
MM.8 SR.17b
MM.8 SR.17c
MM.8 SR.17d
MM.8 SR.17e
MM.8 SR.18
MM.8 SR.18a

1735.6 (c)	Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each
	such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.
1735.7 (a)	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
1735.7 (b)	The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
1735.7 (c)	Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product.
1735.8 (a)	Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
1735.8 (b)	The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
1735.8 (c)	The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

MM.8 SR.18b
MM.8 SR.18b
MM.8 SR.19
MM.8 SR.19a
MM.8 Sr.19a
MM.8 SR.20
MM.8 SR.20a
MM.8 SR.20b

1735.8 (d)	The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.
1751 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
1751 (b)	Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:
1751 (b)1	Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)2	Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)3	Be ventilated in a manner in accordance with Section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations.
1751 (b)4	Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
1751 (b)5	The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

MM.8 SR.20c
MM.8 SR.21
MM.8 SR.22
MM.8 SR.22a
MM.8 SR.22b
MM.8 SR.22c
MM.8 SR.22d
MM.8 SR.22e

1751 (b)6	A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)7	There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.
1751 (c)	Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.
1751.1 (a)	Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
1751.1 (b)	In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:
1751.1 (b)1	The training and competency evaluation of employees in sterile product procedures.
1751.1 (b)2	Refrigerator and freezer temperatures.
1751.1 (b)3	Certification of the sterile compounding environment.
1751.1 (b)4	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
1751.1 (b)5	Inspection for expired or recalled pharmaceutical products or raw ingredients.
1751.1 (b)6	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
1751.1 (c)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

MM.8 SR.22f
MM.8 SR.22g
MM.8 SR.23
MM.8 SR.24
MM.8 SR.24a
MM.8 SR.24a(1)
MM.8 SR.24a(2)
MM.8 SR.24a(3)
MM.8 SR.24a(4)
MM.8 SR.24a(5)
MM.8 SR.24.a(6)
MM.8 SR.24

1751.2	In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile products shall include the following information on the labels for those products:
1751.2 (a)	Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
1751.2 (b)	Name and concentrations of ingredients contained in the sterile injectable product.
1751.2 (c)	Instructions for storage and handling.
1751.2 (d)	All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly."
1751.3 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:
1751.3 (a)1	Compounding, filling, and labeling of sterile injectable compounds.
1751.3 (a)2	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
1751.3 (a)3	Equipment and supplies.
1751.3 (a)4	Training of staff in the preparation of sterile injectable products.
1751.3 (a)5	Procedures for handling cytotoxic agents.
1751.3 (a)6	Quality assurance program.
1751.3 (a)7	Record keeping requirements.
1751.3 (b)	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

MM.8 SR.25
MM.8 SR.25a
MM.8 SR.25b
MM.8 SR.25c
MM.8 SR.25d
MM.8 SR.26
MM.8 SR.26a
MM.8 SR.26b
MM.8 SR.26c
MM.8 SR.26d
MM.8 SR.26e
MM.8 SR.26f
MM.8 SR.26
MM.8 SR.1a

1751.3 (c)	Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
1751.3 (d)	Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
1751.3 (d)1	All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
1751.3 (d)2	All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
1751.3 (d)3	Policies and procedures must address at least the following:
1751.3 (d)3(A)	Competency evaluation.
1751.3 (d)3(B)	Storage and handling of products and supplies.
1751.3 (d)3(C)	Storage and delivery of final products.
1751.3 (d)3(D)	Process validation.
1751.3 (d)3(E)	Personnel access and movement of materials into and near the controlled area.
1751.3 (d)3(F)	Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
1751.3 (d)3(G)	Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

MM.8 SR.27
MM.8 SR.27a
MM.8 SR.27b
MM.8 SR.27c
MM.8 SR.27d
MM.8 SR.27e
MM.8 SR.27f
MM.8 SR.27g

1751.3 (d)3(H)	Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area..
1751.3 (d)3(I)	For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
1751.3 (d)3(J)	Sterilization.
1751.3 (d)3(K)	End-product evaluation and testing.
1751.4 (a)	No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
1751.4 (b)	During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
1751.4 (c)	All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
1751.4 (d)	Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

MM.8 SR.27h
MM.8 SR.27i
MM.8 SR.27j
MM.8 SR.27k
MM.8 SR.23
MM.8 SR.28a
MM.8 SR.28b
MM.8 SR.28c

1751.4 (e)	Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications, Certification records must be retained for at least three years.
1751.5 (a)	When preparing cytotoxic agents, gowns and gloves shall be worn.
1751.5 (b)	When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
1751.5 (b)1	Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
1751.5 (b)2	Cleanroom garb must be donned and removed outside the designated area.
1751.5 (b)3	Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
1751.5 (b)4	Head and facial hair must be kept out of the critical area or be covered.
1751.5 (b)5	Gloves made of low-shedding materials are required.
1751.5 (c)	The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.
1751.6 (a)	Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

MM.8 SR.29
MM.8 SR.30a
MM.8 SR.30
MM.8 SR.30a
MM.8 SR.30b
MM.8 SR.30c
MM.8 SR.30d
MM.8 SR.30a
MM.8 SR.30
MM.8 SR.31

1751.6 (b)	The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
1751.6 (c)	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
1751.6 (d)	The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
1751.6 (e)	Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
1751.6 (e)1	The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
1751.6 (e)1(A)	Aseptic technique.
1751.6 (e)1(B)	Pharmaceutical calculations and terminology.
1751.6 (e)1(C)	Sterile product compounding documentation.
1751.6 (e)1(D)	Quality assurance procedures.
1751.6 (e)1(E)	Aseptic preparation procedures.
1751.6 (e)1(F)	Proper gowning and gloving technique.
1751.6 (e)1(G)	General conduct in the controlled area.
1751.6 (e)1(H)	Cleaning, sanitizing, and maintaining equipment used in the controlled area.
1751.6 (e)1(I)	Sterilization techniques.
1751.6 (e)1(J)	Container, equipment, and closure system selection.

MM.8 SR.31
MM.8 SR.32
MM.8 SR.32
MM.8 SR.32
MM.8 SR.32a
MM.8 SR.32a(1)
MM.8 SR.32a(3)
MM.8 SR.32a(4)
MM.8 SR.32a(8)
MM.8 SR.32a(1)
MM.8 SR.32a(2)
MM.8 SR.32a(2)
MM.8 SR.32a(6)
MM.8 SR.32a(5)
MM.8 SR.32a(7)

	Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and
1751.6 (e)2	continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.
1751.7 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
1751.7 (a)1	Cleaning and sanitization of the parenteral medication preparation area.
1751.7 (a)2	The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
1751.7 (a)3	Actions to be taken in the event of a drug recall.
1751.7 (a)4	Written justification of the chosen expiration dates for compounded sterile injectable products.

MM.8 SR.32
MM.8 SR.32
MM.8 SR.32
MM.8 SR.34a
MM.8 SR.34b / SR.34c
MM.8 SR.34d
MM.8 SR.34e

1751.7 (b)	<p>Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a mar</p>	MM.8 SR.32
1751.7 (c)	<p>Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.</p>	MM.8 SR.34f(1)
1751.7 (d)	<p>Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.</p>	MM.8 34f(2)
1751.8	<p>In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.</p>	MM.8 SR.28d

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
- SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
- SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.
- SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
 - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
 - *All non-controlled substances are to be locked when a patient care area is not staffed.*
 - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices. There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
 - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
 - *Labeling of medications*
 - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
 - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Avoidance of dangerous abbreviations;
- Alert systems for look-like and sound-alike drug names;
- Use of facility approved pre-printed order sheets whenever possible.
- That orders to "resume previous orders" are prohibited;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Drug recalls;
- That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- Identification of when weight-based dosing for pediatric populations is required;
- Other relevant performance improvement activities

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- Verify the process for ensuring correct patient identification
- Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.
- Review the process followed when medications are not given on time and what action(s) are taken

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- name and strength of the drug;

- lot and control number equivalent; and,
- expiration date.

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- Patient's full name;
- the prescriber's name;
- strength and quantity of the drug dispensed; and,
- appropriate accessory and cautionary statements are included as well as the expiration date .

Review and verify that medications provided in floor stock include:

- the name and strength of the drug;
- lot and control number of equivalent; and
- expiration date.

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals

Review the transfusions and intravenous medications practices

- Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices
 - Review the course content to ensure that the following information is included at a minimum:
 - Fluid and electrolyte balance
 - Blood components
 - Venipuncture techniques, returned demonstration and supervised practice

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

- SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
- SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- *Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*
- *Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*
- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*
- *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.
 - SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- *Name of patient;*
- *Age and weight of patient, when appropriate;*
- *Date and time of the order;*
- *Drug name;*
- *Dosage form (e.g., tablets, capsules, inhalants);*
- *Exact strength or concentration;*
- *Dose, frequency, and route;*
- *Quantity and/or duration;*
- *Indication for use when appropriate;*
- *Specific instructions for use; and*
- *Name of prescriber.*

Hospitals should establish policies and procedures that:

- *Describe limitations or prohibitions on use of verbal/telephone orders;*
- *Provide a mechanism to ensure validity/authenticity of the prescriber;*
- *List the elements required for inclusion in a complete verbal/telephone order ;*
- *Describe situations in when verbal/telephone orders may be used;*
- *List and define the individuals who may send and receive verbal/telephone orders; and,*
- *Provide guidelines for clear and effective communication of verbal/telephone orders.*

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.
- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in this area shall be segregated and unavailable.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - SR.5a potential drug-drug interactions;
 - SR.5b potential allergies or cross sensitivities;
 - SR.5c proper dose ranges; and,
 - SR.5d proper indications for administration.
- SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- *The practitioner caring for the patient must determine the urgency of administration;*
- *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
- *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*
- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
- *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
- *All high-risk medications in this area shall be segregated and unavailable;*
- *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
 - *potential drug-drug interactions;*
 - *potential allergies or cross sensitivities;*
 - *proper dose ranges, and*
 - *proper indications for administration.*
- *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
- *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.
- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

- SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.
- SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:
- SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and
 - SR.3b is reasonable considering the intended use of the compounded medication; and
 - SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:
- SR.4a Active ingredients to be used.
 - SR.4b Inactive ingredients to be used.
 - SR.4c Process and/or procedure used for preparation of the drug product.
 - SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
 - SR.4e Post-compounding process or procedures required, as applicable.
 - SR.4f Dates of expiration/use by dates as required.
- Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.
- SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.
- SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.
- SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.
- SR.11 For each compounded drug product, the pharmacy records shall include:
- SR.11a The master formula record.
 - SR.11b The date the drug product was compounded.
 - SR.11c The name of the pharmacy personnel who compounded the drug product.

- SR.11d The name of the pharmacist reviewing the final drug product.
- SR.11e The quantity of each component used in compounding the drug product.
- SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
- SR.11g The equipment used in compounding the drug product.
- SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
- SR.11i The expiration date of the final compounded drug product.
- SR.11j The quantity or amount of drug product compounded.

- SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.
- SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).
- SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.
- SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.
- SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:
 - SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.
 - SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.
 - SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
- SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

- SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.
- SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.
- SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .
- SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.
- SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.
- SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.
- SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.
- SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.
- SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.
- SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:
- SR.22a Clean Room and Work Station Requirements.
- SR.22b Construction of walls, ceilings and floors.
- SR.22c Maintain appropriate ventilation of the preparation area.
- SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.
- SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.
- SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.

SR.24a(2) Monitoring of refrigerator and freezer temperatures.

SR.24a(3) Certification of the sterile compounding environment.

SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).

SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

SR.25b Name and concentrations of ingredients contained in the sterile injectable product.

SR.25c Instructions for storage and handling

SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.

SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

SR.26c Equipment and supplies used.

SR.26d Training of staff regarding the preparation of sterile injectable products.

SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).

SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation

SR.27b Storage and handling of products and supplies.

SR.27c Storage and delivery of final products.

SR.27d Process validation of processes.

SR.27e Personnel access and movement of materials into and near the controlled area.

SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

- SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
- SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
- SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- SR.27j Sterilization.
- SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

- SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:
 - SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.
 - SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.
 - SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.
 - SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.
- SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.
- SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:
 - SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
 - SR.30b Clean room attire must be donned and removed outside the designated area.
 - SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).
- SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

- SR.32a(1) Use of aseptic preparation technique and procedures.
- SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
- SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
- SR.32a(4) Documentation of Sterile product compounding.
- SR.32a(5) Appropriate use of sterilization techniques.
- SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- SR.32a(7) Selection of containers, equipment, and closure system.
- SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall be documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.

SR.34b Storage of compounded sterile injectable products in the Pharmacy

SR.34c Periodic documentation of refrigerator temperatures.

SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.

SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.

SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- Altering the dosage form or delivery system of a drug
- Altering the strength of a drug
- Combining components or active ingredients
- Combining components or active ingredients
- Preparing a drug product from chemicals or bulk drug substances

“Compounding” does not include:

- does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product.

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

ISO Class 7 guidelines are met when particulate contamination is measured at “not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room).”

ISO Class 8 guidelines are met when particulate contamination is measured at “not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area).”

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- compounding of drugs*
- compounding sterile injectable products from one or more non-sterile ingredients*
- preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

1735.2 (a)	Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
1735.2 (b)	A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
1735.2 (c)	Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
1735.2 (c)1	is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
1735.3 (c)2	is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
1735.2 (c)3	for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
1735.2 (d)	A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
1735.2 (d)1	Active ingredients to be used.
1735.2 (d)2	Inactive ingredients to be used.
1735.2 (d)3	Process and/or procedure used to prepare the drug.

MM.8 SR.1
MM.8 SR.2
MM.8 SR.3
MM.8 SR.3a
MM.8 SR.3b
MM.8 SR.3c
MM.8 SR.4
MM.8 SR.4a
MM.8 SR.4b
MM.8 SR.4c

1735.2 (d)4	Quality reviews required at each step in preparation of the drug.
1735.2 (d)5	Post-compounding process or procedures required, if any.
1735.2 (d)6	Expiration dating requirements.
1735.2 (e)	Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
1735.2 (f)	The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
1735.2 (g)	All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
1735.2 (h)	Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
1735.2 (i)	The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

MM.8 SR.4d
MM.8 SR.4e
MM.8 SR.4f
MM.8 SR.11
MM.8 SR.5
MM.8 SR.7
MM.8 SR.8
MM.8 SR.5

1735.2 (j)	Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
1735.3 (a)	For each compounded drug product, the pharmacy records shall include:
1735.3 (a)1	The master formula record.
1735.3 (a)2	The date the drug product was compounded.
1735.3 (a)3	The identity of the pharmacy personnel who compounded the drug product.
1735.3 (a)4	The identity of the pharmacist reviewing the final drug product.
1735.3 (a)5	The quantity of each component used in compounding the drug product.
1735.3 (a)6	The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
1735.3 (a)7	The equipment used in compounding the drug product.

MM.8 SR.10
MM.8 SR.11
MM.8 SR.11a
MM.8 SR.11b
MM.8 SR.11c
MM.8 SR.11d
MM.8 SR.11e
MM.8 SR.11f
MM.8 SR.11g

1735.3 (a)8	A pharmacy assigned reference or lot number for the compounded drug product.
1735.3 (a)9	The expiration date of the final compounded drug product.
1735.3 (a)10	The quantity or amount of drug product compounded.
1735.3 (b)	Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
1735.3 (c)	Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.
1735.3 (d)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.
1735.4 (a)	In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
1735.4 (b)	A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
1735.4 (c)	Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

MM.8 SR.11h
MM.8 SR.11i
MM.8 SR.11j
MM.8 SR.12
MM.8 SR.13
MM.8 SR.12
MM.8 SR.14
MM.8 SR.15
MM.8 SR.16

1735.5 (a)	Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
1735.5 (b)	The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
1735.5 (c)	The policy and procedure manual shall include the following:
1735.5 (c)1	Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
1735.5 (c)2	Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
1735.5 (c)3	The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
1735.5 (c)4	Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
1735.5 (c)5	Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
1735.6 (a)	Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
1735.6 (b)	Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

MM.8 SR.17
MM.8 SR.17
MM.8 SR.17
MM.8 SR.17a
MM.8 SR.17b
MM.8 SR.17c
MM.8 SR.17d
MM.8 SR.17e
MM.8 SR.18
MM.8 SR.18a

1735.6 (c)	Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.
1735.7 (a)	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
1735.7 (b)	The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
1735.7 (c)	Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product.
1735.8 (a)	Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
1735.8 (b)	The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
1735.8 (c)	The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

MM.8 SR.18b
MM.8 SR.18b
MM.8 SR.19
MM.8 SR.19a
MM.8 Sr.19a
MM.8 SR.20
MM.8 SR.20a
MM.8 SR.20b

1735.8 (d)	The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.
1751 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
1751 (b)	Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:
1751 (b)1	Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)2	Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)3	Be ventilated in a manner in accordance with Section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations.
1751 (b)4	Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
1751 (b)5	The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

MM.8 SR.20c
MM.8 SR.21
MM.8 SR.22
MM.8 SR.22a
MM.8 SR.22b
MM.8 SR.22c
MM.8 SR.22d
MM.8 SR.22e

1751 (b)6	A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations.
1751 (b)7	There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.
1751 (c)	Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.
1751.1 (a)	Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
1751.1 (b)	In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:
1751.1 (b)1	The training and competency evaluation of employees in sterile product procedures.
1751.1 (b)2	Refrigerator and freezer temperatures.
1751.1 (b)3	Certification of the sterile compounding environment.
1751.1 (b)4	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
1751.1 (b)5	Inspection for expired or recalled pharmaceutical products or raw ingredients.
1751.1 (b)6	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
1751.1 (c)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

MM.8 SR.22f
MM.8 SR.22g
MM.8 SR.23
MM.8 SR.24
MM.8 SR.24a
MM.8 SR.24a(1)
MM.8 SR.24a(2)
MM.8 SR.24a(3)
MM.8 SR.24a(4)
MM.8 SR.24a(5)
MM.8 SR.24.a(6)
MM.8 SR.24

1751.2	In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile products shall include the following information on the labels for those products:
1751.2 (a)	Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
1751.2 (b)	Name and concentrations of ingredients contained in the sterile injectable product.
1751.2 (c)	Instructions for storage and handling.
1751.2 (d)	All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly."
1751.3 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:
1751.3 (a)1	Compounding, filling, and labeling of sterile injectable compounds.
1751.3 (a)2	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
1751.3 (a)3	Equipment and supplies.
1751.3 (a)4	Training of staff in the preparation of sterile injectable products.
1751.3 (a)5	Procedures for handling cytotoxic agents.
1751.3 (a)6	Quality assurance program.
1751.3 (a)7	Record keeping requirements.
1751.3 (b)	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

MM.8 SR.25
MM.8 SR.25a
MM.8 SR.25b
MM.8 SR.25c
MM.8 SR.25d
MM.8 SR.26
MM.8 SR.26a
MM.8 SR.26b
MM.8 SR.26c
MM.8 SR.26d
MM.8 SR.26e
MM.8 SR.26f
MM.8 SR.26
MM.8 SR.1a

1751.3 (c)	Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
1751.3 (d)	Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
1751.3 (d)1	All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
1751.3 (d)2	All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
1751.3 (d)3	Policies and procedures must address at least the following:
1751.3 (d)3(A)	Competency evaluation.
1751.3 (d)3(B)	Storage and handling of products and supplies.
1751.3 (d)3(C)	Storage and delivery of final products.
1751.3 (d)3(D)	Process validation.
1751.3 (d)3(E)	Personnel access and movement of materials into and near the controlled area.
1751.3 (d)3(F)	Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
1751.3 (d)3(G)	Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

MM.8 SR.27
MM.8 SR.27a
MM.8 SR.27b
MM.8 SR.27c
MM.8 SR.27d
MM.8 SR.27e
MM.8 SR.27f
MM.8 SR.27g

1751.3 (d)3(H)	Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area..
1751.3 (d)3(I)	For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
1751.3 (d)3(J)	Sterilization.
1751.3 (d)3(K)	End-product evaluation and testing.
1751.4 (a)	No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
1751.4 (b)	During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
1751.4 (c)	All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
1751.4 (d)	Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

MM.8 SR.27h
MM.8 SR.27i
MM.8 SR.27j
MM.8 SR.27k
MM.8 SR.23
MM.8 SR.28a
MM.8 SR.28b
MM.8 SR.28c

1751.4 (e)	Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications, Certification records must be retained for at least three years.
1751.5 (a)	When preparing cytotoxic agents, gowns and gloves shall be worn.
1751.5 (b)	When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
1751.5 (b)1	Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
1751.5 (b)2	Cleanroom garb must be donned and removed outside the designated area.
1751.5 (b)3	Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
1751.5 (b)4	Head and facial hair must be kept out of the critical area or be covered.
1751.5 (b)5	Gloves made of low-shedding materials are required.
1751.5 (c)	The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.
1751.6 (a)	Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

MM.8 SR.29
MM.8 SR.30a
MM.8 SR.30
MM.8 SR.30a
MM.8 SR.30b
MM.8 SR.30c
MM.8 SR.30d
MM.8 SR.30a
MM.8 SR.30
MM.8 SR.31

1751.6 (b)	The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
1751.6 (c)	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
1751.6 (d)	The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
1751.6 (e)	Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
1751.6 (e)1	The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
1751.6 (e)1(A)	Aseptic technique.
1751.6 (e)1(B)	Pharmaceutical calculations and terminology.
1751.6 (e)1(C)	Sterile product compounding documentation.
1751.6 (e)1(D)	Quality assurance procedures.
1751.6 (e)1(E)	Aseptic preparation procedures.
1751.6 (e)1(F)	Proper gowning and gloving technique.
1751.6 (e)1(G)	General conduct in the controlled area.
1751.6 (e)1(H)	Cleaning, sanitizing, and maintaining equipment used in the controlled area.
1751.6 (e)1(I)	Sterilization techniques.
1751.6 (e)1(J)	Container, equipment, and closure system selection.

MM.8 SR.31
MM.8 SR.32
MM.8 SR.32
MM.8 SR.32
MM.8 SR.32a
MM.8 SR.32a(1)
MM.8 SR.32a(3)
MM.8 SR.32a(4)
MM.8 SR.32a(8)
MM.8 SR.32a(1)
MM.8 SR.32a(2)
MM.8 SR.32a(2)
MM.8 SR.32a(6)
MM.8 SR.32a(5)
MM.8 SR.32a(7)

	Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and
1751.6 (e)2	continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.
1751.7 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
1751.7 (a)1	Cleaning and sanitization of the parenteral medication preparation area.
1751.7 (a)2	The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
1751.7 (a)3	Actions to be taken in the event of a drug recall.
1751.7 (a)4	Written justification of the chosen expiration dates for compounded sterile injectable products.

MM.8 SR.32
MM.8 SR.32
MM.8 SR.32
MM.8 SR.34a
MM.8 SR.34b / SR.34c
MM.8 SR.34d
MM.8 SR.34e

1751.7 (b)	Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a mar
1751.7 (c)	Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
1751.7 (d)	Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.
1751.8	In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

MM.8 SR.32
MM.8 SR.34f(1)
MM.8 34f(2)
MM.8 SR.28d

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-02

DATE: October 3, 2008
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Approval of Deeming Authority of Det Norske Veritas Healthcare, Inc. for Hospitals

Memorandum Summary

This memorandum announces the Centers for Medicare & Medicaid Services' (CMS) decision to approve Det Norske Veritas Healthcare, Inc. (DNV Healthcare) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare program.

Section 1865(b) of the Social Security Act (the Act) permits providers and suppliers accredited by an approved national accrediting body to be "deemed" to meet Medicare Conditions for Coverage or Participation. To receive approval, accreditation organizations must demonstrate to CMS that their requirements meet or exceed the Medicare conditions.

CMS reviewed DNV Healthcare's application for approval of deeming authority for hospitals in accordance with 42 CFR 488.4 and 42 CFR 488.8. CMS' review included DNV Healthcare's survey and accrediting process as well as its health and safety standards. CMS' review found DNV Healthcare's accreditation program for hospitals to meet or exceed the Medicare Conditions of Participation (CoP).

CMS announced DNV Healthcare's approval as a deemed status accreditation program for hospitals in the September 29, 2008, *Federal Register* (see attachment A). This is an initial 4 year approval effective September 26, 2008 through September 26, 2012. Deeming authority for this program is limited to the Medicare CoPs and does not apply to ownership, enrollment, or other Medicare requirements. Attachment B contains talking points for use by Regional Office and State Agency staff.

This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association. DNV Healthcare's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital CoPs.

Page 2 – State Survey Agency Directors

If you have any questions regarding this memorandum, please contact Cindy Melanson at 410-786-0310 or via E-mail at cindy.melanson@cms.hhs.gov.

Effective date: Immediately. The State agency should disseminate this information within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with relevant survey and certification staff, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management

**CMS-2895-FN Approval of Det Norske Veritas Healthcare, Inc. for
Deeming Authority for Hospitals**

- This notice announces our decision to approve Det Norske Veritas Healthcare, Inc. (DNVHC) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare or Medicaid programs.
- This is an initial 4-year approval effective September 26, 2008 through September 26, 2012.
- This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association.
- DNVHC's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital conditions of participation.



NIAHOSM Accreditation Program
Accreditation Process
Revision 12

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DNV HEALTHCARE INC

NIAHOSM ACCREDITATION PROGRAM

ACCREDITATION PROCESS

INTRODUCTION

The National Integrated Accreditation for Healthcare Organizations (NIAHOSM) is a program offered by DNV Healthcare Inc. (DNVHC) and is the first integrated accreditation program for hospitals in the United States. Integrated Accreditation utilizes two or more independent sets of standards in the same survey process to produce one set of outcomes.

The NIAHOSM Hospital Accreditation Program integrates ISO 9001 Quality Management System requirements with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482) (CoPs). Healthcare systems that want to participate in the Medicare program must be found to be in compliance with the CoPs by the Centers for Medicare and Medicaid Services (CMS). CMS makes that determination by its own survey process through state agencies or by accepting the accreditation of a private national accreditation organization that has been approved by CMS to deem healthcare organizations in compliance with the CoPs.

DNVHC has been approved by CMS for deeming authority to determine healthcare organizations in compliance with the Conditions of Participation for Hospitals (CoPs) effective September 26, 2008. Compliance with the ISO 9001 standard must occur within three (3) years after the first deemed NIAHOSM accreditation survey.

This Accreditation Process addresses healthcare organizations that are either applying for DNV Healthcare Inc. accreditation or are currently accredited by DNVHC. When a healthcare organization has applied for but not received DNVHC accreditation, it is referred to as an "Applicant Organization." When a healthcare organization is currently accredited by DNVHC, it is referred to as an "Accredited Organization."

ACCREDITATION, MEDICARE DEEMED STATUS, AND ISO COMPLIANCE OR CERTIFICATION TIME FRAMES

A Medicare deemed status survey will consist of a survey for compliance with the NIAHOSM accreditation standards and compliance with or Certification to the ISO 9001 Quality Management System within three years of initial NIAHOSM accreditation. **Compliance** to ISO 9001 requirements must be done through DNVHC. **Certification** to ISO 9001 can be achieved either through DNVHC or by another Accredited Registrar as outlined in NIAHOSM Standard QM.1, SR 1-3.

Continuing NIAHOSM accreditation will require a successful annual survey that validates continuing compliance with NIAHOSM Standards as well as continued ISO 9001 compliance or Certification following the ISO 9001 three-year grace period described in the above Introduction.

Once ISO 9001 compliance or Certification is achieved, continued compliance or Certification will depend on annual ISO Periodic Surveys (limited in scope to full ISO compliance or Certification Survey) and a full ISO compliance or Certification Survey done triennially. The triennial ISO compliance or Certification Survey as well as the annual ISO Periodic Surveys, done in intervening years, will take place concurrently with the annual NIAHOSM Accreditation Survey.

Assuming the Applicant Organization elects to obtain NIAHOSM Accreditation and ISO 9001 compliance or Certification at the same time, the schedule of Surveys will typically take place according to the following schedule:

Initial 3 Year Contract

- Year One: NIAHOSM Accreditation Survey (informal ISO 9001 education will also take place)
- Year Two: NIAHOSM Accreditation Survey and ISO 9001 Pre-Assessment Survey
- Year Three: NIAHOSM Accreditation Survey and ISO 9001 Stage One (where is the hospital on their ISO journey and what is left to be done)

Second 3-Year Contract

- Year One: NIAHOSM Accreditation Survey and ISO 9001 Stage 2 (Certification or Compliance)
- Year Two: NIAHOSM Accreditation Survey and ISO Periodic Survey
- Year Three: NIAHOSM Accreditation Survey and ISO 9001 Periodic Survey

Third 3-Year and All Subsequent Contracts

- Year One: NIAHOSM Accreditation Survey and ISO 9001 Re-Certification or Continued Compliance)
- Year Two: NIAHOSM Accreditation Survey and ISO Periodic Survey
- Year Three: NIAHOSM Accreditation Survey and ISO 9001 Periodic Survey

Failure to obtain this ISO Compliance or Certification in this timeframe will result in Accreditation Jeopardy Status for the Accredited Organization.

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to a State Agency, CMS surveyor, or DNV Healthcare Inc, (DNVHC) staff, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The NIAHOSM Accreditation Requirements and Interpretive Guidelines, and CMS State Operations Manual (SOM) provide the policies and procedures regarding NIAHOSM survey activities.
- The ISO 9001 (Quality Management System [QMS]) and ISO 14001 (Environmental Management System [EMS]) and ISO 19011 (Guidelines for Quality and/or Environmental Management Systems Auditing as well as related NIAHOSM Standards and Interpretive Guidelines provide the basis for the ISO survey activities

Surveyors assess the organization's compliance with the NIAHOSM Standards for all services and locations in which the provider receives reimbursement for patient care services billed under its provider number. Surveyors assess the organization's compliance with the applicable ISO Standards for all services and locations included in the organization's scope statement.

All hospital surveys are unannounced. DNVHC will not provide hospitals with advance notice of the upcoming survey.

SURVEYS AND CLASSIFICATIONS

Annual NIAHOSM Accreditation Survey and ISO 9001 Compliance or Certification Survey

The length of the Accreditation/Compliance/Certification Survey and the number of survey team members are determined by the size and complexity of the Applicant Organization and will be determined in the application process. Regardless of the size and complexity of the Applicant Organization, the team will consist of at least two members, a nurse or physician and a Physical Environment Specialist. The following activities apply whether the survey is for a *combined* ISO and NIAHOSM or just ISO. In any of these survey scenarios the team shall include at least the following activities:

- Introduction to the Applicant Organization and discussion with the Applicant Organization's leadership, to include executive and medical staff leadership and board members;
- Document Review (3-6 hours, depending on size of the Applicant Organization);

The Team Leader will request that the following documents be produced no later than 3 hours after the request is made. If available, a hard copy of the documents requested is preferred. Computer access is also acceptable.

The Team Leader may use a worksheet to give to the facility for obtaining this information;

- Organizational Chart
- Organizational chart for nursing services
- A map/floor plan, indicating locations for patient care and treatment areas
- A list of current inpatients with each patient's room number, age, primary diagnosis, attending physician, admission date, and other significant information as it applies to that patient.
- Current Surgical Schedule
- Most recent ISO certification report unless provided by DNV
- Most recent healthcare accreditation report (if applicable)
- Bylaws of the Governing Body
- Minutes of the Governing Body
- Medical Staff Bylaws, Rules and Regulations
- Minutes of the Medical Executive Committee
- Organizational Plan for Patient Care/Scope of service for each department and patient care unit
- Minutes of the Quality Oversight/Management Review Committee – including Performance Improvement data for the previous 12 months
- Minutes from Environment of Care/Safety Committee
- Management plans for the physical environment and annual evaluations
- List of contracted services, companies and individuals- Surveyors will select a sample for review
- Nursing service plan of administrative authority/delineation of responsibilities for delivery of pt. care
- Infection Control Plan with risk assessment/hazard vulnerability analysis
- List of employees including name, title, unit, and hire date
- List of current patients who have had restraint or seclusion used during hospitalization
- List of patients discharged with the past 6 months who had restraint or seclusion used violent or self-destructive behavior during their hospitalization
- P&P: Autopsies
- P&P: Blood & Blood Product Administration
- P&P: History and Physical Examination
- P&P: Informed Consent
- P&P: Medication Security
- P&P: Moderate Sedation
- P&P: Patient Assessment (Nursing, respiratory, nutritional services, etc.)
- P&P: Pain Management
- P&P: Patient Care Planning/Interdisciplinary Treatment Plan
- P&P: Patient Grievance
- P&P: Procedural Verification Process (Practices ensuring the correct patient, site & procedure)

- P&P: Restraint or Seclusion
- P&P: Verbal/Telephone Orders

As applicable, to assess compliance with the ISO 9001 requirements the following documents will also be incorporated into this review process.

- Control of Documents;
- Control of Records;
- Control of Non-Conformity;
- Internal Reviews (Internal Audits);
- Corrective Action;
- Preventive Action;
- Quality Manual;
- Quality Policy;
- Quality Objectives;
- Management Reviews, and
- Various policies and procedures
- Leadership Interview following document review for clarification of any identified issues;
- Using Tracer Methodology, department/patient unit audits to include staff interviews and open medical record review as appropriate (both clinical and support departments)
 1. The department/units of the organization will be surveyed through the use of tracer methodology. Use of tracer methodology shall be the means by which the surveyors will select records and then follow the patient care and other process(es) to verify various aspects of the organization as they are applied against the NIAHOSM and ISO 9001 standards and organization policies.
 2. The organization can expect visits to multiple areas of the organization to include, but not limited to, patient care units, ancillary services, human resources/personnel office, medical staff office, purchasing, bio-med/clinical engineering and/or facilities management.
 3. The Tracer methodology process may identify performance issues as a result of reviewing an individual patient's case, in one or more steps in the process or perhaps the interfaces between steps that affect the care of the patient/family as well as staff and organization performance.
- Human Resources Interview to verify compliance with staff requirements
- Medical Staff credentialing session to verify compliance with Medical Staff requirements
- Building Tour (4-12 hours, dependent on Applicant Organization size);
- Interviews with individuals who oversee core processes (e.g. patient safety and infection control, etc.) and appropriate staff if deemed necessary by survey findings;
- Interviews with leadership, other management staff, physicians, and board members
- Interviews with patients
- Additional document review if deemed necessary by survey findings;
- Oral presentation of Preliminary Findings to Applicant Organization Leadership Team.

ACCREDITATION AND CERTIFICATION PROCESS

The Accreditation and Certification process begins when the Applicant Organization submits a completed DNV Healthcare Inc. Accreditation Application, to include an ISO 9001 Certification Application if DNVHC is to be the ISO Registrar. Upon receipt of a completed Application(s), DNVHC will review the information and provide a fee structure based on the Applicant Organization's complexity and services requested.

For new enrollees in the Medicare program and prior to issuance of a quote for an accreditation survey, the applicant organization must submit evidence of its 855A completeness notification by CMS. A survey may only be scheduled if the applicant organization has received their 855A enrollment completeness notification from CMS.

If the Applicant Organization requires a Business Associate Agreement, it must be submitted to DNVHC and executed prior to the on-site survey.

DNVHC shall identify a survey team to conduct the on-site survey and confirm acceptable dates when the survey may be conducted. As the survey is unannounced, the survey team and the dates will NOT be shared with the Applicant Organization.

Following the on-site accreditation survey the Applicant Organization will be made aware that the next survey (pending closure of any open issues) will occur any time from the ninth to the fifteenth month following the initial Accreditation Survey. The same timeframes will apply for subsequent NIAHO surveys conducted by DNVHC.

SURVEY LOCATIONS

For hospitals with either no or a small number of off-campus provider-based locations, the team will survey all departments, services, and locations that bill for services under the organization's provider number and included in the scope statement (as ISO required) and are considered part of the organization.

For organizations with many provider-based locations survey:

- All hospital departments and services at the primary organization campus and on the campuses of other remote locations of the hospital
- All satellite locations of the hospital
- All inpatient care locations of the hospital
- All out-patient surgery locations of the hospital
- All locations where complex out-patient care is provided by the hospital
- The surveyors will select a **sample** of each type of other services provided at additional provider-based locations.

CONTRACTED SERVICES

On any organization NIAHO survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on organization campuses or organization provider based locations should be surveyed as part of the organization for compliance with appropriate requirements.

SURVEY TEAM SIZE AND COMPOSITION

DNVHC decides the composition and size of the team. In general, a suggested survey team for a full survey of a mid-size (200 bed) hospital would typically include 3 surveyors who will be at the facility for 2 or more days. Each hospital survey team will include at least one RN or Physician with hospital survey experience and a Physical Environment Specialist as well as other surveyors who have the training and expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census and number of employees
- Complexity of services offered, including outpatient services
- Type of survey to be conducted
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints

Prior to the on-site survey, DNVHC shall verify that all members of the survey team have confirmed that there is no present conflict of interest and they have in no manner assisted the Applicant Organization in preparation or otherwise served in the capacity as a consultant or as a former or current employee of the Applicant Organization. In the event a conflict of interest is apparent or suspected, DNVHC will remove any surveyor and replace that individual with another surveyor free of any conflict of interest.

TRAINING FOR SURVEYORS

Clinical, Physical Environment, and Generalist Surveyors must successfully complete the following:

- The DNVHC NIAHOSM Surveyor Training
- The DNV Quality Lead Auditor or an equivalent course accredited by IRCA or RAB-QSA
- The DNV Risk-Based Certification methodology training
- Orientation to DNVHC policies, procedures and software requirements

Additionally, the Physical Environment Specialists must successfully complete the following:

- Successful completion of a NFPA (National Fire Protection Association) Life Safety Code training with an additional focus on hospital requirements.
- Alternatively, 5 years or more of experience within facilities management including safety programs, direct involvement in the environment where patient care services are provided and knowledge of the Life Safety Code will satisfy this requirement.

LEAD SURVEYOR (TEAM LEADER)

The survey is conducted under the leadership of a Lead Surveyor (Team Leader), designated by DNVHC staff. The Lead Surveyor (Team Leader) is responsible for assuring that all survey activities are completed within the specified time frames and in a manner consistent with this protocol and other DNVHC policies and procedures. Responsibilities of the Lead Surveyor (Team Leader) include:

- Acting as the spokesperson for the team on site
- Facilitating management of the survey
- Encouraging communication among team members
- Evaluating team progress and coordinating meetings with team members and hospital staff as needed
- Coordinating any ongoing conferences with organization leadership and providing feedback, as appropriate, to organization leadership on the status of the survey
- Facilitating Opening and Closing Meetings
- Coordination and preparation of Preliminary Survey Report, with active participation of all survey team members
- Submission of preliminary report to DNVHC

SURVEY PLAN PREPARATION

The objective of this activity is to analyze information about the organization in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the organization (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, scope statement, etc.) require additional surveyors to the team beyond those assigned based on average daily census, number of employees and complexity of the organization. Information obtained about the organization will also allow DNVHC to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated annually using the completed organization application)

Currently accredited organizations will be required to provide information to DNVHC by completing an Annual Update to the application. The information contained within the Annual Update will identify:

- Accurate contact information for the organization
- Names of members of Senior Leadership
- Any off-site locations that have been added since the prior survey
- Volume information from the prior year of the annual survey
- Any new services that have been added since the prior survey
- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc). (If applicable)
- If applicable review previous survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings
- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc).
- The annual survey will be unannounced.

SURVEY TEAM OFF-SITE SURVEY PREPARATION

The survey team should prepare for the survey offsite by sharing organization pertinent information so they are ready to begin the survey immediately upon entering the facility. This can best be accomplished electronically (from the Lead Surveyor (Team Leader) to other team members) with a follow-up conference call if necessary. The following should be included in this preliminary exchange and/or discussion:

- Organization demographics & services offered
- Layout of facility if available
- Survey schedule
- Timing of survey activities, including beginning and ending times
- Suggested lodging and transportation options
- Directions to facility

SURVEY TEAM ARRIVAL

The entire survey team should enter the organization together. Upon arrival, surveyors shall present their identification along with the announcement letter to the receptionist or other hospital representative upon entering the building.

The Lead Surveyor (Team Leader) will announce to the CEO or Executive in charge or organization contact, that a survey is being conducted. If the CEO (or executive in charge) is not onsite or available, the Lead Surveyor (Team Leader) will ask that they are notified that a survey is being conducted. The Survey Team will not delay the survey because the CEO or other hospital staff is/are not on site or available.

OPENING MEETING

- Explanation of the purpose, scope of the survey, and provide a schedule of survey activities to the organization (the schedule may be adjusted as necessary)
- Brief explanation of the survey process;
- Introduction of survey team members, including any additional surveyors who may join the team at a later time, the general area that each will be responsible for, and the various documents that they may request;
- Clarification of all organization areas and locations, departments, and patient care settings under the hospital provider number and/or scope statement that will be surveyed, including any contracted patient care activities or patient services located on organization campuses or organization provider based locations
- Discuss the location (e.g., conference room) where the team may meet privately during the survey
- A telephone and internet connection for team communications (or access to these services if needed), preferably in the team meeting location
- Determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey.
- Propose a preliminary date and time for the Closing Meeting.
- During the Opening Meeting, the Lead Surveyor (Team Leader) will request that the organization provide the survey team with the documents requested for Document Review as listed. The Lead Surveyor (Team Leader) will request that the documents be produced no later than 3 hours after the request is made.

INITIAL ON-SITE SURVEY TEAM MEETING

After the conclusion of the Opening Meeting, the survey team will meet in order to evaluate information gathered, and modify surveyor assignments, as necessary. The surveyors will not delay the continuation of the survey process waiting for information from the organization, but rather will adjust survey activities as necessary. During the on-site team meeting, team members should:

- Review the scope of hospital services
- Identify hospital locations to be surveyed, including any off-site locations
- Adjust surveyor assignments, as necessary, based on information provided
- Discuss issues such as change of ownership, adverse events, construction activities, and disasters, if they have been reported
- Make an initial patient sample selection (The patient list may not be available immediately after the opening meeting and the team may delay completing the initial patient sample selection a few hours as meets the needs of the survey team)

PATIENT SAMPLE SIZE AND SELECTION

To select the patient sample, the surveyors will review the patient list provided and select patients who represent a cross-section of the patient population and the services provided. Patient logs (ER, OB, OR, restraint, etc) may be

used in conjunction with the patient list to assure the sample is reflective of the scope of services provided by the organization.

Whenever possible and appropriate, select patients that are in the facility during the time of survey (i.e., open records). Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through record reviews with observations and patient and staff interviews. There may be situations where closed records are needed to supplement the open records reviewed (e.g., too few open records, complaint investigation, etc), surveyors will use their professional judgment in these situations and select a sample size that will enable them to make compliance determinations and verify consistency.

If it is necessary to remove a patient from the sample during the survey, (e.g., the patient refuses to participate in an interview), the surveyors will replace the patient with another who fits a similar profile. This will be done as soon as possible in the survey.

The number of clinical records selected for review will typically be based on the organization's Average Daily Census (ADC). A guiding principle when selecting clinical records is to consider 10% of the ADC as sufficient to determine compliance in most instances in a hospital with an ADC of 180 or more. For smaller hospitals the sample should not be fewer than 10 inpatient records, provided that the number of records is adequate to determine compliance with any given requirement.

Within the sample, the surveyors will select at least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc). In addition to the inpatient sample, the surveyors will select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations. The sample size may be expanded as needed to assess the organization's compliance with all applicable standards.

If a complaint is being investigated during the survey, the survey team will include patients who have been identified as part of the complaint in the sample. Issues or concerns identified through complaints may be an area of focus when selecting the patient sample.

SURVEYOR INFORMATION GATHERING AND INVESTIGATION

The objective of this activity is to determine the hospital's compliance with the requirements through observations, interviews, and document review.

- The surveyors will focus attention on actual and potential patient outcomes, as well as required processes.
- The surveyors will assess the care and services provided, including the appropriateness of the care and services within the context of the Standards.
- The surveyors will visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
- The surveyors will observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.

DURING THE SURVEY

Typically the survey team will be accompanied by assigned organization staff as the survey is conducted. However the surveyors have discretion whether to allow, or refuse to allow, organization staff to accompany the surveyors during a survey or a selected activity of the survey. Surveyors will make a decision whether to allow organization staff to accompany them based on the circumstances at the time of the survey activity.

The survey team will meet at least daily (typically each morning) with organization leadership in order to assess the status of the survey, progress of completion of assigned activities, areas of concern, and to identify areas for additional investigations. The meetings will include an update by each surveyor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the survey team and the organization staff will coordinate efforts to obtain additional information, if appropriate. The organization staff will have the opportunity to present additional information or to offer explanations concerning identified issues. Survey information will not be discussed unless the investigation process and data collection for the specific concerns is completed.

Additional team meetings can be called at any time during the survey to discuss crucial problems or issues. Any significant issues or significant adverse events must be brought to the Lead Surveyor's attention immediately.

Although non-consultative information may be provided upon request, the surveyor is not a consultant. However, it is common to educate the hospital staff on aspects of the requirements and their application to the hospital processes.

PATIENT CARE REVIEW

A comprehensive review of care and services received by patients in the sample will be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, the surveyors will observe sample patients receiving treatments (e.g., intravenous therapy, tube feedings, wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

SURVEYOR ASSESSMENTS

The team will observe the care environment to obtain information about how the care delivery system works and how the organization's departments work together to provide care. Surveyors will review services provided, conduct interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review the surveyor may also observe patient care, the environment, staff interactions with patients, safety hazards, infection control practices, or any other activity that affects patient care or staff performance.

During the survey, the surveyors will pay particular attention to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present as well as those that are not present that should be present;
- Integration of all services to determine that the facility is functioning as one integrated whole
- Whether quality improvement is a organization-wide activity, incorporating every service and activity of the organization
- Whether every organization department and activity reports to and receives reports from the organization's quality management oversight, facilitating the organization-wide quality management system.
- Awareness and the effectiveness of the hospital's quality management system
- Storage, security and confidentiality of medical records.

Surveyors will record notes of findings/issues and should document for objective evidence:

- The date and time of the observation(s)
- Location
- Patient identifiers
- Individuals present during the observation
- Activity being observed (e.g., therapy, treatment modality, etc).
- Document / Form names and/or numbers (if applicable)

The surveyor will try to have findings verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding an out-dated medication in the pharmacy, the surveyor will ask the pharmacist to verify that the drug is out-dated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

INTERVIEWS

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews will be conducted throughout the survey. The surveyors will use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews, the surveyors will do the following:

- Maintain documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.
- The surveyors will conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interviews may include patient rights, advanced directives, and the facility's grievance/complaint procedure.
- Interviews with patients will be conducted in private and with the patient's prior permission.

- The surveyors will interview staff to gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview will be addressed in the staff interview in order to validate the patient's perception or to gather additional information.
- Telephone interviews will be conducted if necessary, but the preference is for in-person interviews.
- The surveyors will integrate the data from interviews with data gathered through observations and document reviews.

ORGANIZATION DOCUMENTATION

Documents reviewed by the survey team during the survey, in addition to the formal Document Review, may be both written and electronic and include the following:

- Patient's clinical records to validate information gained during the interviews as well as for evidence of advanced directives, discharge planning instructions, patient teaching etc. This review will provide a broad picture of the patient's care.
- Plans of care and discharge plans should be initiated immediately upon admission, and be modified as patient care needs change. As an example, the record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes.
- Although team members may have a specific area assigned during the survey, the team will avoid duplication of efforts during review of medical records and each surveyor will typically review the record as a whole instead of targeting the assigned area of concern.
- Surveyors should use open patient records rather than closed records whenever possible
- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the hospital at the time of the survey. (For example, if there are no obstetrical patients in the facility at the time of the survey, the surveyors will review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records.)
- In the review of closed clinical records, the surveyors will review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.
- Personnel files to determine if staff members have the appropriate educational and training, pre-employment requirements, competency/performance assessments, and are licensed if it is required;
- Physician and allied health credential files to determine if the facility complies with Standards requirements and State law and follows its own written policies for medical staff privileges and credentialing;
- Maintenance and calibration records to determine if equipment is periodically attested and/or calibrated to determine if it is in good working order and if environmental requirements have been met
- Staffing documents to determine if adequate numbers of staff are provided according to the number and acuity of patients
- Policy and Procedure Manuals
- Contracts, if applicable
- Organization activities minutes as requested

ANALYSIS OF FINDINGS

The objectives of this survey team meeting are to integrate findings, review and analyze all information collected from surveyor observations, interviews, and record reviews, and to determine whether or not the organization meets the appropriate Standard requirements. Each team member will review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team. Based on the team's decisions, additional activities may need to be initiated. The meeting will include the following: The surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. Decisions about deficiencies will be based on input from the team members but the final decision shall always be the responsibility of the Lead Surveyor (Team Leader).

- The team will document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of any facility Nonconformity.
- The team will ensure that their findings are supported by adequate documentation of surveyor observations, interviews and document reviews.

- Any additional documentation or evidence needed to support identified Nonconformities should be gathered prior to the Closing Meeting but at a minimum, prior to exiting the hospital.

When a deficient practice (Nonconformity) is determined to have taken place prior to the survey and the organization states that it has corrected the deficient practice/issue, the survey team will consider the following:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Has the organization implemented the corrective action(s)?
- Has the hospital taken a quality management approach to the corrective action to ensure monitoring, tracking and sustainability?
- The survey team will use their judgment to determine if any corrective action(s) taken by the organization prior to the survey is sufficient to correct the Nonconformity and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected **prior** to the survey, the survey team **will not cite** the Nonconformity.
- If a Nonconformity with any requirement is noted **during** the survey, even when the hospital corrects the Nonconformity during the survey, the Nonconformity shall be cited.

CLOSING MEETING

- The Lead Surveyor (Team Leader) is responsible for organization of the presentation of the closing meeting.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the closing, they should immediately contact the DNVHC office
- The facility determines which hospital staff will attend the closing meeting.
- The Lead Surveyor (Team Leader) will explain how the team will conduct the closing meeting and any associated ground rules.
- Ground rules will include waiting until the surveyor finishes discussing a given deficiency before accepting comments from facility staff.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference by which identity might be deduced
- The surveyor will present the findings of Noncompliance or Observation, explaining why the finding(s) is a violation. The surveyor will just present the facts.
- If immediate jeopardy is identified by the team, they will explain the significance and the need for immediate correction.
- The organization will have an opportunity to present new information after the closing meeting for consideration after the survey.
- The team will assure that all findings are discussed at the closing conference.
- If the closing conference was audio or video taped, the Lead Surveyor (Team Leader) must obtain a copy of the tape in its entirety before leaving the facility.

DISCONTINUATION OF THE CLOSING MEETING

It is DNVHC's policy to conduct a closing meeting at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct a closing meeting. For example:

- If the provider is represented by counsel (all participants in the closing meeting should identify themselves), surveyors may refuse to conduct the closing meeting if the attorney tries to turn it into an evidentiary hearing; or
- If the organization leadership creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of a closing meeting, surveyors may refuse to conduct or continue the

closing meeting. Under such circumstances, the Lead Surveyor (Team Leader) will stop the closing meeting and call the DNVHC offices immediately for further direction.

RECORDING THE CLOSING MEETING

If the organization wishes to audio tape the closing meeting, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the meeting. Video taping is also permitted if it is not disruptive to the meeting, and a copy is provided to the Lead Surveyor (Team Leader) at the conclusion of the meeting. It is at the sole discretion of the surveyor(s) to determine if video taping is permitted.

POST-SURVEY ACTIVITIES

- A Preliminary Report shall be completed by the Survey Team and issued to the accredited organization.
- DNVHC will forward the final survey report to the organization within 10 days of the last date of the survey.

SURVEY FINDING DEFINITIONS: NIAHOSM

Nonconformity (NC)- (Category 1)

- Objective evidence exists that a requirement has not been addressed (intent), a practice differs from the defined system (implementation), or the system is not effective (effectiveness).
- The absence of one or more required system elements or a situation which raises significant doubt that the services will meet specified requirements.
- A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to requirement of the standard.
- A category 2 non-conformity that is persistent (or not corrected as agreed by the customer) shall be up-graded to category 1, OR a situation, that, on the basis of available objective evidence, would have the capability to cause patient harm or does not meet a standard of care.
- Condition Level Finding- A Condition Level Finding is a Category 1 Nonconformity in which the customer is determined to be completely or substantially out of compliance with the standard. Such finding is made on a case-by-case basis in DNV Healthcare Inc.'s sole discretion. A Condition Level Finding will be identified as a Category 1 Nonconformity- Condition Level Finding. All Condition Level Findings will require a follow-up survey prior to the next annual survey.
 - For organizations as new enrollees in the Medicare Program, all Category 1 Nonconformities must be closed prior to issuance of the accreditation certificate. If there are any Condition Level Category 1 Nonconformities identified, the customer will be required to complete a full re-survey prior to issuance of an accreditation certificate.

For all other, Category 1 nonconformities, a follow-up survey may be required prior to the next annual survey as specified in 3.5.1 (below)

Nonconformity (NC)- (Category 2)

A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that services will meet requirements. Overall system requirement is defined, implemented and effective.

As applicable a finding as a Category 2 nonconformity may be:

- An isolated non-fulfillment of a standard requirement that is otherwise properly documented and implemented, or,
- Inconsistent practice compared to other areas of the customer, or,
- Significant enough to warrant the customer to take action to prevent future occurrence and/or has the potential for becoming a Category 1 nonconformity.

Customer Follow-up Required for Nonconformities

- A Corrective Action Plan (CAP) must be delivered to DNV Healthcare Inc. within ten (10) calendar days from date of the written report. The CAP must:
 - Identify the root cause that led to the nonconformity;
 - Identify the actions taken to correct the nonconformity in the affected areas and/or processes;
 - Identify other areas and/or processes (if applicable) that have the potential to be affected by the same nonconformity;
 - Identify the process or system changes that will be made to ensure that the nonconformity does not recur;
 - Identify the timeframe for the implementation of the corrective action measure(s);
 - Identify the time of the person responsible for implementing the corrective action measure(s) and,
 - Identify the performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

DNV Healthcare Inc. follow-up with Customer for Nonconformities

DNV Healthcare Inc. will acknowledge receipt of the CAP and state any deficiencies and additional requirements with timelines for submission OR declare acceptance of the submitted documentation.

The customer is expected to implement corrective action measure(s) within sixty (60) days. When this is not feasible DNV Healthcare will consider and evaluate the circumstances involved and approve a suitable timeframe to enable the customer to implement the corrective action measure(s). Although such instances for extending the timeframe will be evaluated on a case-by-case basis, it would be a rare occurrence that the extended timeframe for implementation of corrective action measure(s) to exceed six (6) months.

For Category 1 Nonconformities, within sixty (60) days of DNV Healthcare Inc. acceptance, the customer shall submit performance measure(s) data, findings, results of internal reviews (internal audits), or other supporting documentation, including timelines to verify implementation of the corrective action measure(s). If a Category 1 Nonconformity results in a Condition Level Finding, a follow-up survey prior to the next annual survey will also be required to determine compliance with the specific Category 1 Nonconformity.

For Category 2 Nonconformities, if the corrective action plan(s) requirements are met, validation of effective implementation of the agreed corrective action plan will take place at the next annual survey.

DNV Healthcare Inc. will respond to the customer regarding acceptance of the submitted documentation and identify any deficiencies and additional requirements with time lines for submission.

Failure to comply with the requirements of the CAP regarding nonconformities may also result in a Condition Level Finding. A Condition Level Finding could result in Jeopardy Status for the customer as described in Follow-up and Special Surveys (ICP-12-5-i5) and Jeopardy Status, Withdrawal of Accreditation, Disputes and Appeals (ICP-12-6-i4).

DNV Healthcare Inc., in its sole discretion, shall determine the need for a follow-up survey when compliance and implementation cannot be reasonably determined through written documentation of objective evidence.

The scope and extent of the follow-up survey will be determined based upon the complexity of the nonconformity and one or more surveyors will be assigned to the follow-up survey. When possible, members of the survey team that conducted the survey when the nonconformity was issued will be assigned. When this is not feasible, DNV Healthcare Inc. will assign a surveyor that is familiar with the process and has the qualifications to validate compliance.

NOTE- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, all Category 1 nonconformities must be removed prior to the awarding of accreditation. In addition, if any Category 1 nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

NIAHOSM ACCREDITATION IN JEOPARDY (JEOPARDY STATUS)

NIAHOSM Accreditation in Jeopardy (Jeopardy Status) may be invoked based on the following:

- Customer fails to submit a required Corrective Action Plan and/or related documentation or if established reasonable timelines in a Corrective Action Plan are not met
- Customer fails to maintain the ISO quality management system or be certified to ISO 9001 within 3 years of initial DNV Healthcare Inc following the first NIAHOSM deemed survey.
- Customer violates terms of the signed accreditation agreement, including non-payment of fees or refusal of access.
 - Failure to respond adequately to nonconformities identified during the accreditation process.
 - Customer makes false public claims regarding its accreditation. (e.g., accreditation is used in a way that is unjustifiable or deceptive in advertising.)
 - Information from stakeholders that could affect the status of accreditation (e.g., non-compliance to regulatory/statutory requirements).
 - Individual is delivering patient care or providing services without a required valid license or certification or registration;
 - Preventable issues that pose Immediate Jeopardy (harm or injury to a patient); or,
 - Non-compliance with statutory and regulatory requirements of state and/or federal law.

The requirements that the Accredited Organization must meet to be removed from Jeopardy Status and the length of time an Accredited Organization may remain in Jeopardy Status before Accreditation and Certification are removed will be outlined for the Accredited Organization in the Jeopardy notification. Jeopardy Status notification will outline the length of time the Accredited Organization may remain in Jeopardy Status, but normally that timeframe will not exceed four (4) months. Any extension shall be based on a progressing Corrective Action Plan that has been validated by a Special Survey.

FINDINGS AND WRITTEN REPORT

- o DNV Healthcare Inc. shall provide final written report(s), NIAHOSM and/or ISO 9001, to the Applicant Organization within ten (10) days of the survey. The final written report(s) will contain all identified Nonconformities as well as Opportunities for Improvement relative to the NIAHOSM standards and/or ISO requirements that were identified by the team during the performance of the survey.
- o Following receipt of the final written report(s) the Applicant Organization will have ten (10) days from the date of the Survey report to appeal any Nonconformity findings relative to either NIAHOSM standards or ISO requirements.
- o The Applicant Organization will submit Corrective Action Plan(s) to address the nonconformities identified and return this to DNV Healthcare Inc. If the Corrective Action Plan(s) are approved, the report of nonconformities with the Corrective Action Plan(s) will be submitted to the Accreditation Committee.
- o Based on successful survey findings and/or Action Plan follow-up as described above, this will be presented to the Accreditation Committee for their decision regarding the accreditation status of the applicant organization. If approved, the Applicant Organization will receive a three year DNV Healthcare Inc. NIAHOSM Accreditation and, if appropriate, a three year Certification or Compliance for meeting the ISO 9001 Quality Management System requirements, subject to the approval of the Certification Body for ISO 9001.
- o In order to maintain accreditation, the organization will be subject to annual surveys for assessment of continual compliance with the NIAHOSM requirements and compliance with corrective action plan(s) from the prior survey.

APPEALS PROCEDURE

Appeals received by DNV Healthcare Inc. shall be:

- o Registered in a log to record the progress to completion;
- o Acknowledged by DNV Healthcare Inc. without undue delay; and,
- o Reviewed and answered.

The appeal is not bound to a particular form or content. However, the appeal shall be submitted in writing stating the basis of the appeal and the relief being requested. The appeal can be faxed, e-mailed or sent by US mail to:

Darrel J. Scott, Senior Vice President, Regulatory & Legal Affairs
DNV Healthcare Inc.
463 Ohio Pike, Suite 203
Cincinnati, Ohio 45255
Fax: (513) 947-1250
Email: Darrel.Scott@dnv.com

The appellant shall be informed of the right to:

- o Present its case in person
- o Appeal to the President of DNV Healthcare Inc. if the appellant does not accept the decision of the Executive Vice President, Accreditation.

The following applies for all appeals:

The decision reached by the Executive Vice President, Accreditation or President shall be communicated to the appellant in writing

- o If the appellant still remains dissatisfied with the decision of the Executive Vice President, Accreditation or President, the appellant is entitled to one (1) appeal to the Standards and Appeals Board.
- o Any appellant notice that it will pursue a remedy beyond DNV Healthcare Inc. shall be reported to DNV Corporate Legal Affairs through the Vice President, Regulatory Affairs.
- o The Executive Vice President of Accreditation and President, if appropriate, shall review the final outcome of all appeals to determine the need for any change in DNV Healthcare Inc. procedures.

FOLLOW-UP / SPECIAL SURVEY

A Follow-Up Survey will be performed when the following occur

- When compliance regarding a nonconformity has been issued, and cannot be reasonably determined to be corrected and implemented with contact with the organization written documentation of objective evidence;
- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, if any nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

A Special Survey will be performed when the following occur

- Either in response to a patient or patient family complaint to DNV Healthcare Inc.;
- Media coverage of issues and the issue(s) cannot be resolved through DNV Healthcare Inc. evaluation of data findings, internal audits, or other documentation as requested by DNV Healthcare;
- CMS informs DNV Healthcare Inc. of a concern based on information they may have received from another source,; or,
- When a situation within the definition of Immediate Jeopardy is identified.

In those instances where the leadership of the organization is aware of the incident or nonconformity, DNV Healthcare Inc. encourages the organization to contact DNV Healthcare Inc. at the time of the event to discuss a process for resolution or when feasible to respond to the respective nonconformity. The Special Survey will focus on the issues and associated processes surrounding the incident or nonconformity. These Special Surveys will be unannounced.

Any Follow-Up or Special Survey will be done at the expense of the organization. The costs will be based on those in the basic DNV Healthcare Inc. fee schedule in effect at the time of the Follow-Up or Special Survey. DNV Healthcare Inc. will forward a written Report to the organization within ten (10) days, outlining the requirements, timelines, and required follow-up for any Corrective Action Plan(s).

NIAHOSM SURVEY REPORTS

DNVHC shall have a Lead Surveyor (Team Leader) evaluate all survey findings and provide a final report and any other appropriate information to the DNVHC Accreditation Committee. The DNVHC Accreditation Committee will make the final decision on granting or withholding DNVHC NIAHOSM Accreditation. The final accreditation decision will be sent to the Applicant/Accredited Organization upon the organization's completion of the correction action plan(s) within the applicable timeframes and acceptance of the plan(s) by DNVHC. The Applicant/Accredited Organization shall have one opportunity to appeal the DNVHC Accreditation Committee decision or any associated findings for a period of fifteen (15) days following the final decision date of the DNVHC Accreditation Committee. The DNVHC Accreditation Committee decision on the Applicant/Accredited Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

ISO 9001 CERTIFICATION/SURVEILLANCE AUDIT REPORTS

DNVHC shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on granting or withholding ISO 9001 Certification. The final Certification Status will be sent to the Organization within forty-five (45) days of the Survey. The Organization shall have the opportunity to appeal the Certification Body decision or any associated findings for a period of fifteen (15) days following the final decision date of the Certification Body. The Certification Body's decision on the Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

Once certified to ISO 9001, the organization will undergo annual periodic audits to maintain compliance or Certification. DNV Healthcare Inc. shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on continuing or determining the need to proceed with withdrawing ISO 9001 Certification if the audit findings warrant such action being taken. The organization will be notified of the decision of the Certification Body within forty-five (45) days. If a decision is made to proceed to withdraw the certification, the organization will be provided the appropriate information for remedying this and what subsequent actions that needs to be taken.

CHANGES IN ACCREDITATION REQUIREMENTS

DNVHC shall provide notice to DNVHC Accredited Organizations of any changes or additional requirements in the NIAHOSM Accreditation Program. The notice shall contain a description of the change(s) or additional requirement(s), the effective date(s) of the change(s) or additional requirement(s) and the action(s) required of DNVHC Accredited Organizations to meet the changes.

DNVHC Accredited and Compliant or Certified Organizations will have the opportunity to comment on proposed change(s) or additional requirement(s) for a period of no less than thirty (30) days prior to the DNVHC effective date of the change(s) or additional requirements. Any changes as required by CMS to be made to the NIAHOSM standards must be implemented immediately.

DNV HEALTHCARE INC. RESPONSE TO A COMPLAINT AGAINST AN APPLICANT OR ACCREDITED ORGANIZATION

DNVHC will respond to any written or verbal complaint received by DNVHC against an organization either accredited by DNVHC or scheduled for a survey to become accredited by DNVHC. A complaint may be received from the Centers for Medicare and Medicaid Services (CMS) or any other federal or state agency with oversight responsibility, a patient or patient family, payer, caregiver, or other interested party. Complaints will be prioritized as follows:

Immediate Jeopardy

- o This complaint category is identified by the hospital's Noncompliance with one or more of the NIAHO requirements that has caused, or is likely to cause, serious injury, harm, impairment, or death of a patient or is an immediate threat to life.
- o All Immediate Jeopardy complaints will result in an on-site Special Survey and investigation within two (2) working days of receipt of the information. A Special Survey for Immediate Jeopardy complaints will be

unannounced. Determination of Immediate Jeopardy may be identified as a result of complaint submitted to DNVHC or identified during an on-site survey.

Operational (Response Required)

- o This complaint category is identified by the hospital's noncompliance with one or more of the NIAHOSM requirements that have caused physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s). A Special Survey is usually not required but may be initiated if it is needed to determine if there was patient harm. If a Special Survey is not conducted, the complaint and resolution would be reviewed at the next survey.
- o The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has caused harm of limited consequence and does not significantly impair the patient's mental, physical state for these types of complaints. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.

Operational (No Response Required)

- o This complaint category is identified when the hospital is in Noncompliance with one or more of the NIAHOSM requirements and has not resulted in any physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s).
- o A Special Survey is usually not required but may be initiated if it is needed to determine to complexity and severity of the complaint.
- o The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has not been determined and has caused harm of limited consequence and/or does not significantly impair the patient's mental, physical state for these types of complaints.
- o The Vice-President for Regulatory and Legal Affairs will contact the organization and verify that the complaint has been addressed and resolved internally. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.
- o No Action Required – If adequate information has been received about the complaint and the Vice-President for Regulatory and Legal Affairs has contacted the organization and determined that the complaint has been addressed and resolved internally, no further investigation is necessary.

INFORMATION SUPPLIED UPON REQUEST TO CMS OR STATE AGENCIES IN ACCORDANCE WITH DEEMING AUTHORITY OR OTHER REQUIREMENTS

- o The following information will be supplied to CMS or any state agency that has regulatory oversight over the Applicant/Accredited Organization:
- o Complaint information that includes the complaint and selected action(s) taken. If the resolution required a Special Survey and/or a Corrective Action Plan, related documentation will be supplied, including the eventual outcome;
- o Notification of upcoming Surveys, including retrospective dates of unannounced Special Surveys;
- o Survey Reports from Surveys;
- o Corrective Action Plans and related documentation;
- o Notification of an Accredited Organization entering Jeopardy Status, with Corrective Action Plan and timelines for resolution;
- o Notification of removal of Accreditation and Certification following unsuccessful resolution of Jeopardy Status.



National Integrated Accreditation for Healthcare Organizations
(NIAHOSM)
Accreditation Requirements
ISSUE 307-8.0
(Includes inadvertent omission of UR.1, SR.1(d))

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Use of NIAHOSM Accreditation Requirements

Editor's Note

This Revision 8.0 includes an inadvertent omission of UR.1, SR.1(d). UR.1, SR.1(d) is included in the NIAHOSM Interpretive Guidelines and Surveyor Guidance Revision 8.0 and the Crosswalk of the NIAHOSM Accreditation Requirements and the Medicare Conditions of Participation.

Effective Date

These NIAHOSM Accreditation Requirements, Issue 307-8.0 (Revision 8.0) have an Effective Date of 09-18-09.

National Professional Organizations- Standards of Practice

Standards of practice of the national professional organizations referenced in this NIAHOSM Interpretive Guideline and Surveyor Guidance document are consultative and considered in the accreditation decision.

Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this NIAHOSM Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHOSM accreditation requirements.

NIAHO standards are based upon the Center for Medicare and Medicaid (CMS) Conditions of Participation. Hospitals participating in the Medicare and Medicaid program are expected to comply with current Conditions of Participation. When new or revised requirements are published hospitals are expected to demonstrate compliance in a time frame consistent with the effective date published by CMS in the Federal Register.

Life Safety Code®

The Life Safety Code® of the National Fire Protection Association referenced in this NIAHOSM Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHOSM accreditation requirements.

DEFINITIONS

AOA	American Osteopathic Association
AMA	American Medical Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CRNA	Certified Registered Nurse Anesthetist
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHA	Home Health Agency
HVAC	Heating Ventilating and Air Conditioning
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
Life Safety Code	Life Safety Code® of the National Fire Protection Association
LIP	Licensed Independent Practitioner
NFPA	National Fire Protection Association
NLN	National League for Nursing
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General, Department of Health and Human Services
PRN (prn)	Pro re nata, as the occasion arises, when necessary
QIO	Quality Improvement Organization
QMS	Quality Management System
Secretary	Secretary of the Department of Health and Human Services
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SR	Standard Requirement. Additional explanatory information under each major accreditation requirement in this Guide.

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the organization implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the organization are implemented, measured and monitored.

In addition to any other Quality Management System standard, the organization is required to comply with QM.1 at all times as a part of its Quality Management System. Until the organization achieves ISO 9001:2008 Certification, the organization shall follow at a minimum the ISO 9001:2008 methodology specified in QM.2, SR.3 (below).

SR.1 The organization must develop, implement and maintain an ongoing system for managing quality and patient safety.

SR.1(a) As a part of the Quality Management System for addressing performance improvement and patient safety, the organization must select projects or similar activities that focus attention on various processes, functions and areas of the organization.

SR.1(a)(1) The number and scope of these projects or similar activities will be conducted annually and be proportional to the scope and complexity of the organization's operations and services offered.

SR.1(a)(2) These projects or similar activities will be documented to include the rationale for selection and measurable progress achieved.

SR.1(a)(3) If the organization participates in a Quality Improvement Organization (QIO) cooperative project, the organization must demonstrate that information and supporting documentation is provided to the QIO. If the hospital does not participate in a QIO, the projects and activities are required to be of comparable effort.

SR.2 The organization must implement hospital-wide quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.

SR.3 The organization will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

SR.1 Compliance with the ISO 9001 standard must occur within three (3) years after the initial deemed NIAHOSM accreditation. The Organization shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHOSM accreditation survey or maintain Certification through an Accredited Registrar. Only certificates covered by an accreditation by an IAF MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The organization shall maintain ISO 9001 compliance or formal Certification in order remain eligible for NIAHOSM Accreditation.

SR.1a Failure to demonstrate compliance or certification with the ISO 9001 standard within three (3) years after the NIAHOSM accreditation that first occurs after DNVHC receives deeming authority from CMS shall result in NIAHOSM Jeopardy Status.

SR.2 An Accredited Registrar recognized by the International Organization of Standardization shall meet the following minimum criteria:

SR.2a. shall be accredited for IAF Scope 38; and,
SR.2b. must have certified or conducted a pre-assessment at a minimum of twelve (12) hospitals.

SR.3 The organization will initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1 SR.1. At a minimum the organization must be able to demonstrate at the time of the NIAHOSM Accreditation survey evidence of the following:

SR.3a Control of Documents: the organization's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;

SR.3b Control of Records: the organization ensures that suitable records are maintained for the CoP and NIAHOSM requirements;

SR.3c Internal Surveys (Internal Audits) – the organization conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective;

SR.3d The organization has established measurable quality objectives and the results are analyzed addressed; and

SR.3f Appropriate information has been submitted to the oversight group for quality management as required in QM.6 SR.1 as well as top management for review and analysis during a management review process.

QM.3 QUALITY OUTLINE

The organization shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

QM.4 MANAGEMENT REPRESENTATIVE

A management representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the Quality Management System are implemented and maintained.

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any variation, deficiency or non-conformity identified by the organization shall be addressed by the organization. Appropriate corrective or preventive action will be determined, applied, and documented. Documentation of activities may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific Improvement Project analysis, etc. This documentation shall become a part of the Management Review performed at regular intervals, at a minimum of once annually.

QM.6 SYSTEM REQUIREMENTS

In establishing the Quality Management System, the organization shall be required to have the following as a part of this system:

SR.1 Interdisciplinary group to oversee the Quality Management System that includes at least the CEO, COO, Nurse Executive, Pharmacy, Risk Management, Safety Management, Privacy Officer, Quality Facilitator/Management Representative, and two members of the medical staff who must be doctors of medicine or osteopathy. This interdisciplinary group shall conduct Management Reviews;

SR.2 Written document defining the Quality Management System, to include all clinical and non-clinical services;

SR.3 Statement of the Quality Policy;

SR.4 Measurable Quality Objectives; and,

SR.5 Goal Measurement / Prioritization of activities based in some manner to:

SR.5a Focus on high-risk, problem-prone areas, processes or functions,

SR.5b Consider the incidence, prevalence and severity of problems in these areas, processes or functions,

SR.6c Affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The organization shall evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service. The monitoring shall include the use of internal reviews (audits) of each department or service at scheduled intervals, not to exceed one year and data related to these processes. Individual(s) not assigned to that department or service shall conduct the internal review (audit). Measurement, monitoring and analysis of processes throughout the organization require established measures that have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The organization must define the frequency and detail of the measurement. Those functions to be measured at a minimum must include the following:

SR.1 Threats to patient safety;

SR.2 Medication therapy/medication use; to include medication reconciliation and the use of dangerous abbreviations;

SR.3 Operative and invasive procedures; to include wrong site/wrong patient/wrong procedure surgery

SR.4 Anesthesia/moderate sedation;

SR.5 Blood and blood components

SR.6 Restraint use/seclusion;

SR.7 Effectiveness of pain management system;

SR.8 Infection control system, including nosocomial infections;

SR.9 Utilization Management System;

SR.10 Patient flow issues, to include reporting of patients held in the Emergency Department or the PACU in excess of eight hours.

SR.11 Customer satisfaction, both clinical and support areas;

SR.12 Discrepant pathology reports;

SR.13 Unanticipated deaths, non-sentinel event;

SR.14 Sentinel event/near miss and other medical errors;

SR.15 Other adverse events;

SR.16 Critical and/or pertinent processes, both clinical and supportive;

SR.17 Medical record delinquency; and,

SR.18 Physical Environment Management Systems

QM.8 PATIENT SAFETY SYSTEM

- SR.1 The organization shall have a means for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.
- SR.2 The organization's Patient Safety System shall be documented and shall address the following:
- SR.2a. detection;
 - SR.2b. preventative and corrective action;
 - SR.2c. defined processes to reduce risk;
 - SR.2d. implementation of action plans;
 - SR.2e. on-going measurement to ensure action effectiveness;
 - SR.2f. management review of response and resource allocation to the results of patient adverse event and other analysis; and,
 - SR.2g. policy and practice of informing patients and/or their families about unexpected adverse events.

GOVERNING BODY (GB)

GB.1 LEGAL RESPONSIBILITY

The organization shall have an effective governing body legally responsible for the conduct of the organization as an institution. The governing body is responsible for all services provided in the organization including all contracted services. If an organization does not have an organized governing body, the persons legally responsible for the conduct of the organization must carry out the functions specified.

- SR.1 The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials (to include the chief executive officer, chief financial officer, and nurse executive) are responsible and accountable for ensuring that the following:
- SR1a. the organization is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;
 - SR1b. the organization is licensed by the appropriate State or local authority responsible for licensing hospitals;
 - SR1c. Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the organization, directly or under contract, and/or appointed through the formal medical staff appointment process; and,
 - SR1d. the personnel working in the organization are properly licensed or otherwise meet all applicable Federal, State and local laws.

GB.2 INSTITUTIONAL PLAN AND BUDGET

- SR.1 The organization shall have an overall plan that includes an annual operating budget that contains all anticipated income and expenses and is prepared according to generally accepted accounting principles.
- SR.2 The plan must provide for capital expenditures for at least a 3-year period including the year identified in SR.1 (above). The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or lesser amount established by the State in which the organization is located in accordance with Section 1122(g)(1) of the Social Security Act and is related to:
- SR2a. acquisition of land;
 - SR2b. improvement of land, buildings and equipment, or
 - SR2c. replacement, modernization or expansion of buildings or equipment.

- SR.3 The plan must be reviewed and updated annually.
- SR.4 The plan must be prepared under the direction of the governing body and by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.
- SR.5. If required, the plan must be submitted for review in accordance with Section 1122 of the Social Security Act or, as applicable, to the appropriate health planning agency in the State.

GB.3 CONTRACTED SERVICES

- SR.1 The governing body shall require annual management reviews of selected indicators to ensure that all contracted services (including all joint ventures or shared services) provide services that are safe and effective and that comply with all applicable NIAHOSM requirements.
- SR.2 The governing body is responsible for services furnished in the hospital whether or not they are furnished under contract. The organization must evaluate and select contracted services (including all joint ventures or shared services) (and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection will include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with all applicable NIAHOSM requirements, and standards required for all contracted services.
- SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.

CHIEF EXECUTIVE OFFICER (CE)

CE.1 QUALIFICATIONS

The governing body must appoint a chief executive officer who is qualified through education and experience to be responsible for managing the organization.

CE.2 RESPONSIBILITIES

The chief executive officer is responsible for operating the organization, according to the authority conferred by the governing body. The chief executive officer shall provide for the organization's compliance with applicable law and regulation, including State licensure laws.

MEDICAL STAFF (MS)

MS.1 ORGANIZED MEDICAL STAFF

The organization shall have an organized medical staff that is composed of fully licensed doctors of medicine or osteopathy. In accordance with State law, the medical staff may also include other practitioners.

MS.2 ELIGIBILITY

The governing body shall determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

MS.3 ACCOUNTABILITY

The medical staff shall be organized in a manner approved by and accountable to the governing body and shall be responsible for the quality of the medical care provided to patients.

MS.4 RESPONSIBILITY

The responsibility for organization and conduct of the medical staff must be assigned to an individual doctor of medicine or osteopathy or, when permitted by State law, a doctor of dental surgery or dental medicine.

MS.5 EXECUTIVE COMMITTEE

- SR.1 The medical staff shall meet at regular intervals and minutes shall be maintained. If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.
- SR.2 The chief executive officer and the nurse executive of the organization or designee shall attend each executive committee meeting on an ex-officio basis, with or without vote.

MS.6 MEDICAL STAFF PARTICIPATION

The medical staff shall participate in at least the following organization activities:

- SR.1 Medication management oversight;
- SR.2 Infection control oversight;
- SR.3 Tissue review;
- SR.4 Utilization review;
- SR.5 Medical record review; and,
- SR.6 Quality Management System.
- SR.7 Reports and recommendations from these activities shall be prepared and shared with the medical executive committee and the governing body:

MS.7 MEDICAL STAFF BYLAWS

- SR.1 The medical staff shall be appointed by the governing body and operate under bylaws, rules and regulations adopted and enforced by the medical staff and approved by the governing body.
- SR.2 Changes to the medical staff bylaws, rules and regulations shall require approval of the medical staff and the governing body.
- SR.3 The medical staff bylaws shall describe the organization of the medical staff and include a statement of the duties and privileges of each category of medical staff to ensure that acceptable standards are met for providing patient care for all diagnostic, medical, surgical and rehabilitative services.
- SR.4 Medical staff bylaws shall include provisions for mechanisms for corrective action, including indications and procedures for automatic and summary suspension of medical staff membership or clinical privileges.

MS.8 APPOINTMENT

The medical staff bylaws shall describe the qualifications to be met by a candidate in order for the medical staff to recommend that the governing body appoint the candidate. Those qualifications shall include the following:

- SR.1 Initial appointment to the medical staff:
 - SR.1a. primary source verification of licensure, education, specific training, experience, and current competence ;
 - SR.1b. current Federal Narcotics Registration Certificate (DEA) number;

SR.1c. two peer recommendations;

SR.1d. review of involvement in any professional liability action; and,

SR.1e. if available, review of individual performance data for variation from benchmark. Variation shall go to peer review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies.

SR.2 Reappointment to the medical staff:

SR.2a. primary source verification of licensure and current competence;

SR.2b. current DEA number;

SR.2c. review of involvement in any professional liability action; and,

SR.2d. review of individual performance data for variation from benchmark. Variation shall go to Peer Review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies.

MS.9 PERFORMANCE DATA

Practitioner specific performance data is required and must be rate-based with comparative peer or national data available for comparison. Areas to be measured are:

SR.1 Blood use: AABB transfusion criteria;

SR.2 Prescribing of medications: Prescribing errors and appropriateness of prescribing for Drug Use Evaluations;

SR.3 Surgical Case Review: appropriateness and outcomes for selected high-risk procedures;

SR.4 Specific department indicators that have been defined by the medical staff;

SR.5 Moderate Sedation Outcomes;

SR.6 Appropriateness of care for non-invasive specialties;

SR.7 Utilization data;

SR.8 Significant deviations from established standards of practice; and,

SR.9 Timely and legible completion of patients' medical records.

SR.10 Any variant should be analyzed for statistical significance.

MS.10 CONTINUING EDUCATION

All individuals with delineated clinical privileges shall participate in continuing education that is at least in part related to their clinical privileges.

SR.1 This documentation shall be considered in decisions about reappointment or renewal or revision of clinical privileges.

SR.2 Action on an individual's application for appointment /reappointment or initial or subsequent clinical privileges is withheld until the information is available and verified.

MS.11 GOVERNING BODY ROLE

- SR.1 The governing body shall appoint members of the medical staff and approve clinical privileges after considering the recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
- SR.2 The governing body may elect to delegate the authority to render initial appointment, reappointment, and renewal or modification of clinical privileges decisions to a committee of the governing body.
- SR.3 The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.
- SR.4 A complete application shall be acted on within a reasonable period of time, as specified in the medical staff bylaws.

MS.12 CLINICAL PRIVILEGES

- SR.1 The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.
- SR.2 Appointment or reappointments to the medical staff and the granting, renewal, or revision of clinical privileges shall be made for a period defined by State law or if permitted by State law, not to exceed three years.
- SR.3 All individuals who are permitted by the organization and by law to provide patient care services independently in the organization shall have delineated clinical privileges.
- SR.4 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.
- SR.5 The medical staff bylaws shall provide a mechanism for consideration of automatic suspension of clinical privileges in any of the following instances:
 - SR.5a. revocation/restriction of professional license;
 - SR.5b. revocation/suspension/probation of Federal Narcotics Registration Certificate (DEA);
 - SR.5c. failure to maintain the specified amount of professional liability insurance; or,
 - SR.5d. non-compliance with written medical record delinquency or deficiency requirements.
- SR.6 The medical staff bylaws shall provide a mechanism for immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner's Medicare or Medicaid status.
- SR.7 The medical staff bylaws shall contain fair hearing and appeal provisions for any adverse actions regarding the appointment, reappointment, suspension, reduction or revocation of privileges of any individual who has applied for or has been granted clinical privileges.

MS.13 TEMPORARY CLINICAL PRIVILEGES

When dictated by urgent patient care need or when an application is complete without any negative or adverse information before action by the medical staff or governing body, the chief executive officer or designee, may grant temporary clinical privileges:

- SR.1 On the recommendation of the medical executive committee;
- SR.2 For a period of time not to exceed thirty days. Temporary privileges may be extended for two separate 30-day intervals upon approval of the governing body.
- SR.3 Criteria for granting temporary privileges:

- SR.3a. verification of education (AMA/AOA Profile);
- SR.3b. demonstration of current competence;
- SR.3c. verification of State professional licenses;
- SR.3d. receipt of professional references (including current competence); and,
- SR.3e receipt of database profiles from AMA, AOA, NPDB, OIG Medicare/Medicaid Exclusions.

MS.14 CORRECTIVE OR REHABILITATION ACTION

The medical staff bylaws shall provide a mechanism for management of medical staff corrective or rehabilitative action. This documented action may result from unprofessional demeanor and conduct and/or this behavior is likely to be detrimental to patient safety or the delivery of quality care or is disruptive to organization operations. Any officer of the medical staff, the CEO, or any officer of the board may initiate this corrective or rehabilitative action.

MS.15 ADMISSION REQUIREMENTS

Patients are admitted to the organization only on the recommendation of a licensed practitioner permitted by the State to admit patients to the organization.

- SR.1 The governing body shall ensure that every patient is under the care of a:
 - SR.1a. doctor of medicine or osteopathy who may delegate such care to other qualified health care professionals to the extent allowed by State law;
 - SR.1b. doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his/her license;
 - SR.1c. doctor of podiatric medicine, only with respect to functions authorized by State;
 - SR.1d. doctor of optometry who is legally authorized to practice optometry by the State;
 - SR.1e. chiropractor who is licensed by the State and legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; or
 - SR.1f. clinical psychologist (doctoral degree in psychology), but only with respect to clinical psychologist services as defined in 42 CFR §410.71 and only to the extent permitted by State law.
- SR.2. The governing body shall ensure that:
 - SR.2a. a doctor of medicine or osteopathy is on duty or on call at all times; and,
 - SR.2b. a doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified in SR 1b-1f (above) as that scope of practice is defined by the medical staff and State law.

MS.16 MEDICAL RECORD MAINTENANCE

- SR.1 The medical staff bylaws shall include the requirement for the preparation and maintenance of a complete and accurate medical record for each patient and policies and procedures for dealing with medical record delinquencies.
- SR.2 The medical staff bylaws shall require that the medical staff have periodic meetings at regular intervals to review and analyze medical records of the patients for adequacy and quality of care.

MS.17 HISTORY AND PHYSICAL

- SR.1 The medical staff bylaws shall include a requirement that a medical history and physical examination (HP) for each patient shall be done no more than 30 days before or twenty four (24) hours after an admission or registration, but prior to surgery or other procedure requiring anesthesia services and placed in the patient's medical record within twenty four (24) hours after admission. The HP must be in the medical record prior to any high-risk procedure.
- SR.1a. An HP completed within 30 days prior to admission or registration shall include an entry in the medical record documenting an examination for any change in the patient's current medical condition completed by a doctor of medicine or osteopathy, oromaxillofacial surgeon or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.
- SR.1b. This examination and update of the patient's current medical condition shall be completed and placed in the medical record within twenty four (24) hours after admission or registration, but prior to surgery or other procedure requiring anesthesia services.
- SR.2 A doctor of medicine or osteopathy, oromaxillofacial surgeon shall do the HP described above. Alternatively, a physician's assistant or advance practice nurse may perform a history and physical if permitted by State law and scope of practice. The responsible physician must review and approve the history and physical as specified by the medical staff.
- SR.3 The content of the HP examination and applicability shall be determined by the medical staff and may be done by the individuals described in SR. 2 and SR.3 (above). The content of the HP examination will be determined by an assessment of the patient's condition and any co-morbidities in relation to the reason for admission or surgery. This HP examination must be in the medical record prior to any high-risk procedure, surgery or other procedure requiring anesthesia services and within 24 hours of admission or registration as stated in MS.17, SR.1.

MS.18 CONSULTATION

The medical staff shall define in its bylaws the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required.

MS.19 AUTOPSY

- SR 1. The medical staff shall attempt to secure autopsies in all cases of unusual deaths and those of medical-legal and educational interest.
- SR 2. Mechanisms for documenting permission to perform an autopsy shall be defined.
- SR 3. There shall be a system for notifying the medical staff and specifically the attending practitioner when an autopsy is being performed.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

- SR.1 The organization must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care.
- SR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each patient. A registered nurse or licensed practical nurse shall be on duty at all times except in facilities that have been granted a waiver in accordance with § 488.54(c), Federal law, rules or regulations.

- SR.3 The nursing service must develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services must be provided or supervised by a registered nurse.
- SR.4 There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other staff to provide nursing care to all patients as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.
- SR.5 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- SR.6 Non-employee licensed nurses who are working in the organization must adhere to the policies and procedures of the organization. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

NS.2 NURSE EXECUTIVE

- SR.1 The nurse executive must be a licensed registered nurse with either a master degree, actively pursuing a master's degree or equivalent experience in comparable positions.
- SR.2 The nurse executive is responsible for the operation of the service, including determining the types and numbers of staff necessary to provide nursing care for all patient care areas of the organization and standards of nursing practice.

NS.3 PLAN OF CARE

- SR.1 Nursing staff shall develop and maintain a plan of care for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including pain assessment and interventions shall be included in the plan of care, as appropriate.

STAFFING MANAGEMENT (SM)

SM.1 LICENSURE OR CERTIFICATION

The organization shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification as required by the organization and Federal and State law. This written policy shall be strictly enforced and compliance data reported to Quality Management Oversight.

SM.2 PROFESSIONAL SCOPE

All staff, including contract staff, shall function within the limits of their scope of service as defined by their professional practice act, State law, and organization policy at all times. This written policy shall be strictly enforced and variations reported to Quality Management Oversight.

SM.3 DEPARTMENT SCOPE OF SERVICE

Each department, whether clinical or supportive, and each patient unit shall have a written scope of service that includes at least:

- SR.1 The hours of operation;
- SR.2 Patient populations served;
- SR.3 Skill mix;
- SR.4 Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,

- SR.5 Description of assessment and reassessment practices, including timeframes.
- SR.6 The organization shall consolidate these scopes of service, including these staffing requirements, into one organization-wide document.

SM.4 DETERMINING AND MODIFYING STAFFING

- SR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.
- SR.2 This validation shall be done at least monthly and reported to Quality Management Oversight.

SM.5 JOB DESCRIPTION

All staff, whether clinical or supportive, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

SM.6 ORIENTATION

All staff, whether clinical or supportive, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the organization. The orientation shall take place prior to the individual functioning independently in their job.

SM.7 STAFF EVALUATIONS

- SR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators shall then be selected from this complete list of indicators for measurement as outlined below.
- SR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through at least the following:
 - SR.2a variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
 - SR.2b high-risk, low volume procedures;
 - SR.2c new technology/equipment/processes;
 - SR.2d customer satisfaction feedback;
 - SR.2e scheduled training session outcomes;
 - SR.2f staff learning needs assessments that include variations identified through prior staff performance measurement;
 - SR.2g staff feedback;
 - SR.2h medical staff feedback; and,
 - SR.2i requirements of Federal or State law.
- SR.3 Indicator measurement for contract staff may be modified based on organization outcomes and frequency of service of the individual. Modification of this measurement must take place no less than every calendar year and shall be justified by data analysis.
- SR.4 The organization shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching, and mentoring.
 - SR.4a Re-measurement shall follow any intervention.
 - SR.4b The outcomes of this measurement shall be reported in the aggregate to Quality Management Oversight.

- SR.5 The organization shall define a timeframe, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.
- SR.6 The organization shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or organization policy. Compliance with this standard shall be reported to Quality Management Oversight.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
 - SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
 - SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.
- SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

MM.3 SCHEDULED DRUGS

- SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
- SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.
 - SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.
- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in this area shall be segregated and unavailable.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - SR.5a potential drug-drug interactions;
 - SR.5b potential allergies or cross sensitivities;
 - SR.5c proper dose ranges; and,
 - SR.5d proper indications for administration.
- SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

MM.6 OVERSIGHT GROUP

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

SURGICAL SERVICES (SS)

SS.1 ORGANIZATION

- SR.1 If the organization provides surgical services, the services shall be well organized, appropriate to the scope of the services offered, and provided in accordance with acceptable standards of practice. National standards of practice of AORN, CDC, APIC, ASA and other professional organizations are applicable to surgical services.
- SR.2 If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- SR.3 Surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care, and must be consistent with needs and resources.

SS.2 STAFFING AND SUPERVISION

- SR.1 The organization of the surgical services shall be supervised by either a registered nurse with appropriate experience, or by a doctor of medicine or osteopathy.
- SR.2 Under the supervision of a registered nurse, the following personnel comprise the OR staff:
 - SR.2a registered nurses;
 - SR.2b licensed practical nurses; and,
 - SR.2c surgical technologists (operating room technicians).
- SR.3 Qualified registered nurses shall perform circulating duties in the operating room. If a qualified registered nurse is present who is immediately available to respond to emergencies, licensed practical nurses and surgical technologists may assist in circulatory duties under the supervision of that registered nurse, if State law and medical staff policies and procedures permit.

SS.3 PRACTITIONER PRIVILEGES

- SR.1 All practitioners performing surgery shall have surgical privileges established by the organization's department of surgery and medical staff and approved by the governing body. Surgical privileges shall correspond with the established competencies, technical skill and performance, as appropriate of each practitioner.
- SR.2 A current roster of practitioners that specifies their surgical privileges shall be maintained by the department of surgery.
- SR.3 Privileges for general surgery and surgical subspecialties defined with established criteria approved by the medical staff and in accordance with MS.12.

SS.4 HISTORY AND PHYSICAL

- SR.1 Except in emergencies, there must be a complete history and physical in the medical record of every patient prior to surgery or procedure requiring anesthesia services.
- SR.1a a complete history and physical examination must be completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration
- SR.1b when the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.
- SR.2 If the history and physical has been dictated but not yet present in the patient's medical record, the practitioner who admitted the patient shall write a statement to that effect as well as an admission note in the medical record. Such circumstance is acceptable only in a medical emergency and is not applicable for a scheduled surgery.
- SR.3 A properly executed informed consent form for the surgery shall be in the patient's medical record before surgery except in an extreme medical emergency.

SS.5 AVAILABLE EQUIPMENT

The following equipment shall be present and in operating condition in each surgical suite:

- SR.1 Call-in system;
- SR.2 Cardiac monitor;
- SR.3 Resuscitator;
- SR.4 Defibrillator;
- SR.5 Suction equipment; and,
- SR.6 Provisions for emergency airway intervention.

SS.6 OPERATING ROOM REGISTER

The operating room register shall be complete and current.

SS.7 POST-OPERATIVE CARE

- SR.1 There shall be adequate provision for immediate post-operative care.
- SR.2 Equipment, clinical staff, and plan of care provisions as well as criteria for discharge shall be developed and adopted by the medical staff and nurse executive designees.

SS.8 OPERATIVE REPORT

- SR.1 An operative report describing techniques, findings, and tissues removed or altered shall be written or dictated and signed by the surgeon immediately following surgery.
- SR.2 The operative report shall be dictated or written in its entirety before the patient is transferred to the next level of care (e.g. before the patient leaves the post anesthesia care area).

SS.9 IMMEDIATE POST-OPERATIVE NOTE

- SR.1 An immediate postoperative note is required to be written if there is a dictation turn around delay. This shall include identification or description of:
- SR.1a the surgeon and assistants;
 - SR.1b pre-op and post-op diagnosis;
 - SR.1c procedures performed;
 - SR.1d specimens removed;
 - SR.1e blood administered; and,
 - SR.1f any complications.
 - SR.1g type of anesthesia administered
 - SR.1h grafts or implants
- SR.2 If information identified in the post-operative note is available in nursing documentation; it is acceptable if authenticated as accurate by the attending surgeon.

ANESTHESIA SERVICES (AS)

AS.1 ORGANIZATION

- SR 1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the organization.
- SR 2 Anesthesia services shall be appropriate to the scope of the services offered.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following:

- SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist);
- SR.2 A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- SR.3 A certified registered nurse anesthetist (CRNA) as defined in 42 CFR §410.69(b), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;
- SR.4 For CRNAs to operate as licensed independent practitioners, the governor of the State must have received an exemption from CMS for that particular State; or
- SR.5 An anesthesiologist's assistant as defined in 42 CFR §410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available if needed.

AS.3 POLICIES AND PROCEDURES

- SR.1 Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities.
- SR.2 The policies must ensure that the following are provided for each patient:
- SR.2a a pre-anesthesia or pre-sedation evaluation, to include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and privileged to administer anesthesia/sedation, performed no more than 48 hours prior to surgery or procedure requiring anesthesia services;
 - SR.2b an intra-operative anesthesia/sedation record;

SR.2c for inpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia;

SR.2c(1) A post-anesthesia evaluation for anesthesia recovery is required and must be completed in accordance with State law and hospital policies and procedures approved by the medical staff and reflect current standards of care anytime general, regional, or monitored (this would include deep sedation/analgesia has been administered to the patient.

SR.2c(2) If the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged

SR.2d for outpatient surgery, a follow-up report as defined by the medical staff.

LABORATORY SERVICES (LS)

LS.1 ORGANIZATION

SR.1 The organization shall maintain, or have available, adequate laboratory services, either directly or through contractual services, to meet the needs of its patients.

SR.2 The organization shall ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with 42 CFR §493.

SR.3 The organization shall have the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day.

SR.4 A documented scope of laboratory services shall be available to the medical staff.

SR.5 The laboratory shall have policies and practices for proper receipt and reporting of tissue specimens.

SR.6 The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

LS.2 INFECTIOUS BLOOD AND PRODUCTS

Potential human immunodeficiency virus (HIV) or hepatitis C virus (HVC) (*as identified in 21 CFR 610.47*) infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the HIV or HCV on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, and the timing of seroconversion cannot be precisely estimated.

SR.1 If an organization regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products.

SR.2 The agreement shall require that the blood bank promptly notify the organization of the following:

SR.2a Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV or HCV on a later donation; and

SR.2b the results of the FDA licensed, more specific test or other follow-up testing recommended or required by the FDA completed within forty five (45) calendar days after the donor's repeatedly reactive screening test for HIV or HCV.

- SR.2c Within 3 calendar days after the blood bank supplied blood and blood components collected from an infectious donor, whenever such records are available (as set forth at 21 CFR 610.48(b)(3)).
- SR.2d quarantine of blood and blood products pending completion of testing: If the blood bank notifies the organization of the repeatedly reactive HIV or HCV screening test results, the organization shall determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.
- SR.3 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the organization may release the blood and blood products from quarantine.
- SR.4. If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the organization shall dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify the transfusion recipients according to LS.3.
- SR.5 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is indeterminate, the organization must destroy or label prior collections of blood and blood products held in quarantine (as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2)).
- SR.6 The hospital must maintain adequate records which identify the source and disposition of all units of blood and blood components for no less than ten (10) years from the date of disposition in manner reflecting QM.2 SR.3b and are stored in such a manner they are available for prompt retrieval.
- SR.6a The organization will have a plan in place to transfer these records to another hospital or other entity if the hospital ceases its operations for any reason. The organization will have allocated adequate funding to execute this plan when necessary.

LS.3 PATIENT NOTIFICATION

If the organization has administered potentially HIV or HCV infectious blood or blood products, either directly through its own blood bank or under an agreement, or released such blood or blood products to another entity or appropriate individual, the organization shall take the following actions:

- SR.1 Promptly make at least three attempts to notify the patient, and/or patient's attending physician (the physician of record) or the physician who ordered the blood or blood product. (See LS.3 SR.7 regarding notification of legal representative when applicable)
- SR.2 Request that the physician immediately notify the patient, or other individual of the need for HIV testing and counseling.
- SR.3 If the physician is unavailable, declines to make the notification, or later informs the organization that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, legal representative or relative of the need for HIV or HCV testing and counseling.
- SR.4 Document in the patient's medical record the notification or attempts to give the required notification.
- SR.5 Timeframe for notification:

(For donors tested on or after February 20, 2008 – for notifications resulting from donors tested on or after February 20, 2008 as set forth in 21 CFR 610.46 and 21 CFR 610.47):

The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification for no less than twelve (12) weeks unless:

SR.5a the patient is located and notified; or

SR.5b the organization is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the organization's control that caused the notification timeframe to exceed twelve (12) weeks.

(For donors tested before February 20, 2008 – for notifications resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48(b) and (c):

SR.5c The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification and must complete the actions within one (1) year of the date on which the organization received notification from the blood bank.

Note: HCV notification requirements resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48 is set to expire on August 24, 2015.

SR.6 Content of notification: The notification shall include the following information:

SR.6a a basic explanation of the need for HIV or HCV testing and counseling;

SR.6b enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV or HCV testing and counseling; and,

SR.6c a list of programs or places where the patient can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

SR.7 Policies and Procedures: The organization shall establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records. A notification to legal representative or relative shall address the following:

SR.7a if the patient has been adjudged incompetent by a State court, the physician or organization shall notify a legal representative designated in accordance with State law;

SR.7b if the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or organization shall notify the patient or his/her legal representative or relative; and,

SR.7c if the patient is deceased, the physician or organization shall continue the notification process and inform the deceased patient's legal representative or relative.

SR.7d If the patient is a minor, the physician or organization must notify the patient's parents or legal guardian.

LS.4 GENERAL BLOOD SAFETY

For look-back activities only related to new blood safety issues that are identified after August 27, 2007, the organization must comply with FDA regulations as they pertain to blood safety issues in the following areas:

SR.1 Appropriate testing and quarantining of infectious blood and blood components.

SR.2 Notification and counseling of recipients that may have received infectious blood and blood components.

RESPIRATORY CARE SERVICES (RC)

RC.1 ORGANIZATION

- SR.1 The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.
- SR.2 Respiratory care services provided at the organization shall be delivered in accordance with medical staff directives.
- SR.3 There shall be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly.
- SR.4 There shall be appropriate numbers of respiratory therapists, respiratory therapy technicians and other qualified personnel whose training meets the qualifications specified by the medical staff and State law.

RC.2 PHYSICIAN ORDER

An order from a doctor of medicine or osteopathy is required for the provision of respiratory treatments and interventions.

RC.3 POLICIES OR PROTOCOLS

Written policies or protocols shall specify:

- SR.1 Which personnel are qualified to perform specific procedures; and,
- SR.2 The amount of supervision required

RC.4 TESTS OUTSIDE THE LABORATORY

If blood gases or other laboratory tests are performed in the areas other than the lab, including the respiratory care unit, that area shall meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

MEDICAL IMAGING (MI)

MI.1 ORGANIZATION

- SR.1 The organization shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements according to patient needs. The medical imaging services, particularly ionizing medical imaging procedures shall be free from hazards for patients and personnel.
- SR.2 If therapeutic services are also provided, they shall meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements.

MI.2 RADIATION PROTECTION

- SR.1 Proper radiation safety precautions shall be maintained, including adequate shielding for patients, staff, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.
- SR.2 Staff who work in radiation areas shall be monitored continually for the amount of radiation exposure by the use of exposure meters or badge dosimeters. This includes licensed independent practitioners who may be exposed to ionizing radiation during procedures.
- SR.3 Any high radiation readings must be investigated and reported to Quality Management Oversight.

MI.3 EQUIPMENT

- SR.1 Periodic inspection of equipment shall be performed, at least minimally according to manufacturer's recommendations. Hazards shall be identified and promptly corrected.
- SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained.

MI.4 ORDER

Medical imaging services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners approved by the medical staff and the governing body and authorized to order the services.

MI.5 SUPERVISION

- SR.1 A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing medical imaging services and shall interpret those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge.
- SR.2 For purposes of this standard, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

MI.6 STAFF

Only staff designated as qualified by the medical staff, governing body, and State and/or Federal law may use the medical imaging equipment and perform medical imaging procedures.

MI.7 RECORDS

Records of medical imaging services must be maintained, in accordance with Nuclear Regulatory Commission requirements and any other applicable Federal and State law.

MI.8 INTERPRETATION AND RECORDS

- SR.1 The radiologist or other practitioner who interprets radiology images and outcomes must sign the written reports of his/her interpretations.
- SR.2 The organization must maintain the following for at least 5 years:
 - SR.2a copies of reports and printouts; and,
 - SR.2b films, scans, and other image records.

NUCLEAR MEDICINE SERVICES (NM)

NM.1 ORGANIZATION

- SR.1 If the organization provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice as defined by the medical staff. The nuclear medicine services shall be free from hazards for patients and personnel.
- SR.2 The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.
- SR.3 There shall be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.
- SR.4 The qualifications, training, functions, and responsibilities of nuclear medicine staff shall be specified by the service director and approved by the medical staff.
- SR.5 Nuclear medicine services shall be ordered only by practitioners whose scope of Federal or State licensure and defined staff privileges allow such referrals.

NM.2 RADIOACTIVE MATERIALS

- SR.1 Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the medical staff.
- SR.2 The organization must maintain records of the receipt and disposition of radiopharmaceuticals.
- SR.3 In-house preparation of radiopharmaceuticals shall be by or under the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.
- SR.4 If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

NM.3 EQUIPMENT AND SUPPLIES

- SR.1 Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.
- SR.2 The equipment must be maintained in safe operating condition and inspected, tested, and calibrated at least annually by qualified personnel.
- SR.3 Documentation of equipment testing and preventative maintenance shall be maintained.

NM.4 INTERPRETATION

- SR.1 The practitioner approved by the medical staff to interpret diagnostic procedures must sign the interpretation of these tests.
- SR.2 The organization must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.
- SR.3 The organization must maintain copies of nuclear medicine reports for at least five (5) years.

REHABILITATION SERVICES (RS)

RS.1 ORGANIZATION

SR.1 If the organization provides rehabilitation, physical therapy, occupational therapy, audiology or speech pathology services, the service(s) shall be provided in a manner that ensures the patient's health and safety.

RS.2 MANAGEMENT AND SUPPORT

SR.1 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include:

SR.1a a director/manager who has the responsibility for the management, direction and accountability for ensuring services are carried throughout the organization;

SR.1b the director/manager shall have the qualifications, experience and/or training defined by the organization and appropriate for this position;

SR.1c staff who meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

RS.3 TREATMENT PLAN

The organization shall have a written treatment plan that is in accordance with the practitioner's orders who are authorized by the medical staff to order the services. The orders, treatment plan and results, notes and other related documentation shall be maintained in the patient's medical record.

SR.1 The treatment plan and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of § 409.17.

OBSTETRIC SERVICES (OB)

OB.1 COMPLIANCE

Obstetrical services will comply with recommendations of the American College of Obstetrics and Gynecology.

OB.2 ANESTHESIA SERVICES

SR.1 If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with the recommendations of the American Society of Anesthesiology.

SR.2 If a patient has received epidural analgesia, there will be a practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition.

EMERGENCY DEPARTMENT (ED)

ED.1 ORGANIZATION

- SR. 1 The organization must meet the emergency needs of its patients in accordance with acceptable standards of practice.
- SR.2 Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.
- SR.3 The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered.

ED.2 STAFFING

- SR.1 Adequate medical and nursing staff qualified in emergency care, as outlined in the written scope of service, must be present to meet the written emergency procedures and needs determined by the organization.
- SR.2 A qualified registered nurse shall perform patient triage upon presentation to the emergency department.

ED.3 EMERGENCY SERVICES NOT PROVIDED

If emergency services are not provided at the organization, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

ED.4 OFF-CAMPUS DEPARTMENTS

The medical staff shall have written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided.

OUTPATIENT SERVICES (OS)

OS.1 ORGANIZATION

If the organization provides outpatient services, the services shall be appropriately organized and integrated with inpatient services.

OS.2 STAFFING

The organization shall assign an individual to be responsible for outpatient services and have appropriate professional and nonprofessional staff available.

OS.3 SCOPE OF SERVICE

A documented scope of service shall be available for each patient care site that includes core staffing for each site with associated staff responsibilities.

DIETARY SERVICES (DS)

DS.1 ORGANIZATION

- SR.1 Dietary Services are organized processes that shall be carried out internally or through a contract with a nutrition management company that interacts on a regular basis with the medical staff on dietetic policies affecting patient care.

- SR.2 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include a full-time person responsible for the management, direction and accountability for ensuring food and dietetic services are carried out daily throughout the organization. This full-time person shall have the qualifications, experience and training defined by the organization and appropriate for the position;
- SR.3 The full-time person responsible for the management of Food and Dietetic Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the organization.
- SR.4 The organization shall have a qualified dietitian in the organization who is available to address issues, concerns and patient care planning. This dietitian shall be employed by the organization on a full-time or part-time basis or contracted as a consultant for the organization and available as needed.

DS.2 SERVICES AND DIETS

Dietary Services shall be provided and menus/diets offered that meet the needs of the patients. The following criteria shall be applied:

- SR.1 All menus/diets offered must meet the needs of the patients
- SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; and,
- SR.3 All nutritional needs of patients shall be met in accordance with recognized dietary practices that are consistent with the orders of the practitioner or practitioners responsive for the care of the patients.

DS.3 DIET MANUAL

- SR.1 The organization shall maintain a written dietary manual that defines the current therapeutic diets used by the organization.
- SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the medical staff.
- SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The organization shall protect and promote each patient's rights. The organization shall inform, whenever possible, each patient and/or legal representative (as allowed under State law) of the patient's rights in advance of providing or discontinuing care and allow the patient to exercise his or her rights accordingly. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

- SR.1 Beneficiary Notice of non-coverage and right to appeal premature discharge;
- SR.2 Patient participation and means for making informed decisions regarding his/her plan of care;
- SR.3 Information to the patient or family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of treatment or services deemed medically unnecessary or inappropriate;

- SR.4 Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;
- SR.5 Personal privacy;
- SR.6 Provision of care in a safe setting;
- SR.7 Freedom from all forms of abuse or harassment;
- SR.8 Confidentiality of clinical records;
- SR.9 Access information contained in his or her clinical records within a reasonable timeframe; and,
 - SR.9(a) The hospital must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.
- SR.10 Procedure for submission of a written or verbal grievance. (See PR.5 Grievance Procedure)
- SR.11 Pain Management
- SR.12 Other rights defined within the Patient Rights requirements (PR.1 – PR.8)

PR.2 ADVANCE DIRECTIVE

The organization must allow the patient to formulate advance directives and to have organization staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

- SR.1 The organization shall document in the patient's medical record whether or not the patient has executed an advance directive.
- SR.2 The organization shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- SR.3 The organization shall ensure compliance with State law regarding the provision of an advance directive.
- SR.4 The organization shall provide education for staff regarding the advance directive.
- SR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

PR.3 LANGUAGE AND COMMUNICATION

The organization shall inform the patient and/or legal representative of their rights in language or format that the patient and/or legal representative understand.

- SR.1 Organization policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

PR.4 INFORMED CONSENT

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

PR.5 GRIEVANCE PROCEDURE

The organization shall develop and implement a formal grievance procedure for submission of a patient's written or verbal grievance to the hospital, approved by the governing body, that provides for the following:

- SR.1 A list of whom to contact;
- SR.2 The governing body responsibility for effective operation of the grievance process. The governing body must review and resolution of grievances or the written delegation of this function to an appropriate person or committee ;
- SR.3 A process for timely referral of quality of care issues or premature discharge to the Utilization Review, Quality Management or Peer Review functions and Utilization and Quality Improvement Organizations (QIO), as appropriate; and,
- SR.4 Specification of reasonable timeframes for review and response to grievances.
- SR.5 Grievance resolutions must be in writing and directed to the patient. The grievance resolution shall include the following:
 - SR.5a organization contact person;
 - SR.5b steps taken to investigate;
 - SR.5c results of the grievance process; and,
 - SR.5d date of completion.

PR.6 RESTRAINT OR SECLUSION

All patients have the right to be free from physical or mental abuse, and corporal punishment.

All patients have the right to be free from restraint or seclusion, of any form, that is not medically necessary, or that is imposed by staff as a means of coercion, discipline, convenience, or retaliation. Each patient should be treated with respect and dignity.

- SR.1 The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.
 - SR.1a A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
 - SR.1b A restraint includes a drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.
 - SR.1c Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion

Seclusion may only be used for the management of violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

- SR.2 The hospital will keep the patient safe and protect their rights when restraint or seclusion are applied.
- SR.2a. The hospital will have policies and procedures designed to protect patient rights and dignity with regards to the use of restraint and seclusion, and ensure safety of the patient, staff and others. These policies and procedures guide staff in the safe use of restraint or seclusion, and incorporate all elements of the Federal and State regulations.
- SR.2b. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.
- SR.2c. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.
- SR.2d. The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.
- SR.2e. The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.
- SR.2f. Restraint and seclusion may not be used simultaneously, unless the patient is continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.2f(1) This monitoring must be in close proximity to the patient.

SR.2f(2) For the purposes of this provision, "continually" means ongoing without interruption

SR.3 Order for Restraint or Seclusion:

- SR.3a. The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner (LIP) who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law.
- SR.3b. An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;
- SR.3c. An order for restraint or seclusion is never to be written as a standing order or on an as needed basis (PRN).
- SR.3d. The attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.
- SR.3e. Each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient.
- SR.3e(1) Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1- hour for children under 9 years of age.
- SR.3e(2) The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.
- SR.3e(3) After 24 hours, and before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior a physician or other LIP (if allowed by State law) must see and assess the patient.

SR.3e(4) If the restraint or seclusion is discontinued prior to the expiration of the order, a new order must be obtained prior to re-initiation of the restraint or seclusion.

SR.3f. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy, at least each calendar day.

SR.4 One Hour Face-to-Face Evaluation

The condition of the patient must be continuously assessed, monitored, and reevaluated.

SR.4a. When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under PR.7 must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate:

- SR.4a(1) The patient's immediate situation;
- SR.4a(2) The patient's reaction to the intervention;
- SR.4a(3) The patient's medical and behavioral condition; and,
- SR.4a(4) The need to continue or terminate the restraint or seclusion.

SR.4b. If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation.

SR.5 Assessment, Monitoring, and Evaluation of the Restrained or Secluded Patient

SR.5a. The condition of patients in restraint or seclusion is monitored and assessed by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy, at least every 24 hours.

SR.5a(1) Hospital policies address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).

SR.5a(2) Hospital policies guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. (for example, every 15 minutes)

SR.5b. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

SR.5c. The LIP must evaluate the patient even if the patient is removed from restraint prior to the expiration of the order within 24 hours of the order initiation.

SR.5d. If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.5d(1) This monitoring must be in close proximity to the patient.

SR.5d(2) For the purposes of this provision, "continually" means ongoing without interruption

SR.6. Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- SR.6a(1) A description of the patient's behavior and the intervention used;

- SR.6a(2) Alternatives or other less restrictive interventions attempted (as applicable);
- SR.6a(3) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,
- SR.6a(4) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention
- SR.6a(5) The 1-hour face- to-face medical and behavioral evaluation and assessment findings if restraint or seclusion is used to manage violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;
- SR.6a(6) Monitoring and assessment activities
- SR.6a(7) Written modification to the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.
- SR.6a(8) The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.
- SR.6a(9) Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.

SR.6b. In addition, staff must document in the patient's medical record the date and time any death associated with restraint or seclusion use was reported to CMS. (see section on Report of Death)

SR.7 Quality Monitoring

- SR.7a. The use of restraint and seclusion is to be monitored and evaluated on a continual basis as part of the organization's Quality Management System. (See also QM.7.SR.6)
- SR.7b Evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed by the treatment team.
- SR.7c Aggregate data regarding the use of restraint must be collected and analyzed for the identification of patterns and trends. Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

PR.7 RESTRAINT OR SECLUSION: STAFF TRAINING REQUIREMENTS

The patient has the right to safe implementation of restraint or seclusion by trained staff.

- SR.1 Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion
 - SR.1a. Training must occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.
- SR.2 The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:
 - SR.2a. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
 - SR.2b. The use of non-physical intervention skills, including de-escalation and dealing with aggressive behavior;
 - SR.2c. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition;

- SR.2d. The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
 - SR.2e. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
 - SR.2f. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and;
 - SR.2g. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including recertification requirements.
- SR.3 At a minimum, physicians and other LIP's authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of the hospital policy regarding the use of restraint or seclusion.
- SR.3a. Physician and other LIP training requirements must be specified in hospital policy
- SR.4 Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.
- SR.5 The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed

PR.8 RESTRAINT OR SECLUSION: REPORT OF DEATH

- SR.1 Hospitals must report deaths associated with the use of restraint or seclusion directly to CMS in accordance with 42 CFR 482.13(g), the Conditions of Participation, and the State Operations Manual.
- SR.2 Staff must document in the patient's medical record the date and time the death was reported to CMS.

INFECTION CONTROL (IC)

IC.1 INFECTION CONTROL SYSTEM

- SR.1 The organization shall have a process in place, as required and/or recommended by the Centers for Disease Control (CDC) and related professional organizations, to maintain a sanitary environment for organization patients, staff, and others. This process shall provide the means for avoiding and transmitting infections and communicable diseases.
- SR.2 The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization.
- SR.3 The Infection Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.4 The documented process shall define the following:
- SR.4a there shall be a designated Infection Control Officer that has the appropriate qualifications and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases;
 - SR.4b any designated practitioner shall have completed a course in basic surveillance by a recognized body. If in the role five (5) years or longer there must be evidence of pertinent continuing education related to infection control, minimally every two (2) years;
 - SR.4c the process for identifying, reporting, investigating and controlling infections and communicable diseases; and,
 - SR.4d the maintaining and control of records to account for incidents related to infections and communicable diseases.

- SR.5 Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.
- SR.6 The organization, through its chief executive officer, medical staff and nurse executive shall ensure that the Infection Control System and associated activities adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues and provide adequate resources to accomplish the associated activities of the infection control program,
- SR.7 Significant infection control data/information shall be disseminated no less than quarterly to the organization oversight group responsible for the infection control function.
- SR.8 Surveillance methodology shall be appropriate for the population(s) served and approved no less than annually by the Infection Control oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illnesses

MEDICAL RECORDS SERVICE (MR)

MR.1 ORGANIZATION

- SR.1 Administrative responsibility for medical records shall rest with the medical record service of the organization.
- SR.2 The organization shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

MR.2 COMPLETE MEDICAL RECORD

- SR.1 The organization shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- SR.2 The organization shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.
- SR.3 Authenticity and security of all record entries shall be safeguarded.

MR.3 RETENTION

- SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years.
- SR.2 The coding and indexing system shall be designed in such a way that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

MR.4 CONFIDENTIALITY

- SR.1 Confidentiality of patient records shall be assured.
- SR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.
- SR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.
- SR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.5 RECORD CONTENT

SR.1 The medical record shall contain information to:

- SR.1a justify admission and continued hospitalization;
- SR.1b support the diagnosis; and,
- SR.1c describe the patient's progress and response to medications and services

SR.2 All entries shall be:

SR.2a legible, complete, dated and timed; and,

SR.2b authenticated by the person responsible for providing or evaluating the services provided consistent with hospital policy.

SR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

SR.4 All orders must be dated, timed and authenticated promptly by the prescribing practitioner.

SR.5 Verbal orders must be in accordance with Federal and State law and authenticated within forty (48) hours or earlier if required by State law.

SR.5(1) Telephone or verbal orders are to be used infrequently and when used must be accepted only by Personnel authorized by the medical staff and in accordance with Federal and State law.

SR.5(2) Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

SR.5(3) For the limited time period defined in 42 CFR §482.24(c)(1)(ii), all such orders may be dated, timed and authenticated by another practitioner who is responsible for the patient's care as specified in 42 CFR §482.12(c) and who is authorized to write orders in accordance with hospital policy and State law.

MR.6 IDENTIFICATION OF AUTHORS

The organization shall have a system to identify the author of each entry into the medical record.

MR.7 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

SR.1 Evidence of a physical examination, including a health history, must be performed no more than thirty (30) days prior to admission or within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services:

SR.1a the history and physical completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services; and placed in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

SR.1b when the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

SR.2 Admitting diagnosis,

- SR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- SR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,
- SR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,
- SR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition,
- SR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,
- SR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge

DISCHARGE PLANNING (DC)

DC.1 WRITTEN POLICIES

- SR.1 Written policies shall be in place to establish a system for discharge planning that applies to all patients.
- SR.2 At an early stage of hospitalization, all patients who are at risk for negative outcomes without adequate discharge planning shall be identified and a plan developed to account for the patient's needs.
- SR.3 A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge planning evaluation for or upon the request of:
 - SR.3a the patients identified in the above paragraph;
 - SR.3b any patients upon their request;
 - SR.3c a person acting on the patient's behalf; or,
 - SR.3d the patient's physician.

DC.2 DISCHARGE PLANNING EVALUATION

- SR.1 The discharge planning evaluation shall include:
 - SR.1a an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services; and,
 - SR.1b an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the organization.
 - SR.1c A means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services, and must, when possible, respect patient and family preferences when they are expressed.
- SR.2 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.
- SR.3 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.
- SR.4 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan and associated educational materials.

DC.3 PLAN IMPLEMENTATION

- SR.1 The initial implementation of the patient's discharge plan shall be performed by the organization.
- SR.2 Patients shall be transferred or referred with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed.
- SR.3 When the discharge planning evaluation determines a referral is medically appropriate, the organization shall give the patient a list of Medicare-participating providers (including those qualified to receive the patient from the patient's managed care organization where applicable) that are available and serve the geographical area where the patient resides. The organization shall document in the medical record that the patient (or authorized representative) received a copy of the list and was advised of his/her freedom of choice.
- SR.3a The organization must respect the choice of the patient or authorized representative except in unusual circumstances. The organization may not lead, direct, specify or otherwise limit the selection of qualified Medicare-participating providers.
- SR.3b The organization must identify in writing any Medicare-participating providers to which the patient is referred in which the organization has a disclosable financial interest and any Medicare-participating providers that has a disclosable financial interest in the organization. Disclosable financial interests are defined by 42 CFR §420, Subpart C.
- SR.4 When the organization must transfer or refer patients, the necessary medical information and other supporting documentation must be provided to appropriate facilities, agencies or outpatient services as needed, for follow-up or ancillary care.

DC.4 EVALUATION

- SR.1 The discharge plan shall be periodically reevaluated on an on-going basis to provide for changes in the patient's condition or circumstances. The reassessment must include a review of the discharge plans to ensure that they are responsive to discharge needs.
- SR.2 As needed, the patient and family members or interested persons shall be educated to prepare them for post-hospital care.

UTILIZATION REVIEW (UR)

UR.1 DOCUMENTED PLAN

The organization shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients, particularly those patients entitled to benefits under both Medicare and Medicaid. The plan shall include:

- SR.1 Responsibilities and authority for those involved in utilization review activities in a Utilization Review (UR) Committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners as defined in MS.15 (SR.1)
- SR.1(a) A staff committee of the institution; or
- SR.1(b) A group outside the institution established by the local medical society and some or all of the hospitals in the locality; or
- SR.1(c) Established in a manner approved by CMS.

SR.1(d) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as such that;

SR.1(d)(1) The committee or group's reviews may not be conducted by any individual who ;

SR.1(d)(1)(a) Has a direct financial interest (for example, an ownership interest) in the hospital; or

SR.1(d)(1)(b) Was professionally involved in the care of the patient whose case is being reviewed.

SR.2 Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

SR.3 Provision for avoidance of conflict by prohibiting any individual with any financial or professional involvement in the case from participating in the review. This shall be strictly enforced.

SR.4 Review of:

SR.4a. medical necessity of admissions and extended stays;

SR.4b. appropriateness of setting; and,

SR.4c. medical necessity of professional services.

UR.2 SAMPLING

The review may be done before, at or after admission and may be conducted by sampling. The review shall include medical necessity for the following:

SR.1 Admissions;

SR.2 Length of stay; and,

SR.3 Professional services furnished, including medications.

UR.3 MEDICAL NECESSITY DETERMINATION

SR.1 The committee must review professional services, to determine medical necessity and to promote the most efficient use of available health facilities and services.

SR.2 The determination that an admission or continued stay is not medically necessary may be made by two members of the Quality Management Oversight group after the practitioner(s) caring for the patient has (have) been notified and given an opportunity to present his/her views.

SR.2a Practitioner(s), the organization and the patient must receive written notification of a decision that admission or continued stay is determined to be not medically necessary.

SR.2b The notification must be given no later than two (2) days after such decision is made.

UR.4 EXTENDED STAY REVIEW

The utilization review plan must include a process to periodically review all patients who receive services during a continuous period of extended duration.

SR.1 For organizations paid under the prospective payment system, all patients whose length of stay is considered an outlier must be reviewed.

SR.2 All reviews must be conducted no later than seven (7) days after the day required in the utilization review plan.

PHYSICAL ENVIRONMENT (PE)

PE.1 FACILITY

The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special organization services appropriate to the needs of the community.

- SR.1 The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.
- SR.2 The hospital must maintain adequate facilities for its services.
 - SR.2 (a) Diagnostic and therapeutic facilities must be located for the safety of patients.
 - SR.2. (b) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
 - SR.2 (c) The extent and complexity of facilities must be determined by the services offered.
- SR.3 The organization shall have a process in place, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization's patients, staff, and others.
- SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled, investigated, and reported throughout the organization.
- SR.5 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.7 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues.
- SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

PE.2 LIFE SAFETY MANAGEMENT SYSTEM

- SR.1 The organization shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association.
 - SR.1a Effective March 13, 2006 a hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf, Chapter 19.3.6.3.2, exception number 2.
 - SR.1b. A hospital has until March 31, 2006, to replace 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources, Chapter 19.2.9, Emergency Lighting.
- SR.2 Any hospital that on November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code®, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Life Safety Code®.
- SR.3 After consideration of the State survey agency findings, CMS may waive specific provisions of the Life Safety Code®, which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

SR.3a The provisions of the Life Safety Code® do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protect patients.

SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):

The organization shall establish a Life Safety Management System that provides for written fire control processes that contain provisions for:

SR.4a. Use of alarms

SR.4b. Transmission of alarm to fire department

SR.4c. Response to alarms

SR.4d. Isolation of fire

SR.4e. Evacuation of immediate area

SR.4f. Evacuation of smoke compartment

SR.4g. Preparation of floors and building for evacuation

SR.4h. Extinguishment of fire

SR.5 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.

SR.6 Health care occupancies shall conduct unannounced fire drills regularly, but not less than one (1) drill per shift per building each calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. (NFPA 101-2000, 18.7.1.2. & 19.7.1.2). False alarms may be used (up to 50% of total drills) if all elements of the fire plan are exercised.

Business occupancies shall conduct at least one unannounced fire drill annually per shift.

SR.6a. Fire drills must be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2, SR.4

SR.6a.(i) At least annually, the organization shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.

SR.7 The Life Safety Management System shall address applicable Interim Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired, or deficiencies deficient are created or occur. Thorough documentation is required.

SR.7a. All alternative life safe measures must be approved by the authority having local jurisdiction

SR.8 Life Safety Management System shall require that Life Safety systems (e.g., fire alarm suppression, notification, and detection equipment) shall be is tested and inspected (including portable systems).

SR.9 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.

SR.10 The Life Safety Management System shall require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

SR.11 Construction, Repair, and Improvement operations shall involve the following activities:

SR.12.a During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 2006 edition, published by the American Institute of Architects shall be consulted for designing purposes.

- SR.12. b The organization shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).
- SR.12. c In occupied areas where construction, repairs, or improvement operations occur, all required means of egress and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.
NFPA 241-1996, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.
- SR.12. d All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2000 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

PE.3 SAFETY MANAGEMENT SYSTEM

- SR.1 The organization shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients.
- SR.2 The Safety Management System shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.
- SR.3 The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.4 The Safety Management System shall require that the organization maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- SR.5 The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.
- SR.6 The Safety Management System shall address safety recalls and alerts.

PE.4 SECURITY MANAGEMENT SYSTEM

- SR.1 The organization shall develop a Security Management System that provides for a secure environment.
- SR.2 The Security Management System shall provide for identification of patients, employees and others.
- SR.3 The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.
- SR.4 The Security Management System shall establish emergency security procedures to include all hazard events
- SR.5 The Security Management System shall require vehicular access to emergency service areas.
- SR.6 The Security Management System shall require a process for reporting and investigating security related issues.

PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT SYSTEM

- SR.1 The organization shall provide a Hazmat Management System to manage hazardous materials and waste.

- SR.2 The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3 The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4 The organization monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.
- SR.5 Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if:
- SR.5a. Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
 - SR.5b. The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
 - SR.5c. The dispensers are installed in a manner that adequately protects against inappropriate access
 - SR.5d. The dispensers are maintained in accordance with dispenser manufacturer guidelines.
 - SR.5e. If dispensers are stored in corridors, the corridor must be a minimum of 72 inches.
 - SR.5f. The maximum individual dispenser fluid capacity shall be:
 - 1.2 liters (0.3 gallons) for dispensers in rooms, corridors, and areas open to corridors.
 - 2.0 liters (0.5 gallons) for dispensers in suites of rooms.
 - SR.5g. The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.
 - SR.5h. Not more than an aggregate 37.8 liters (10 gallons) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.
 - SR.5i. Storage of quantities greater than 18.9 liters (5 gallons) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*.
 - SR.5j. The dispensers shall not be installed over or directly adjacent to an ignition source.
 - SR.5k. In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.
 - SR.5l. Where minimum corridor width is 72 inches (1830 mm), projections of maximum 6 inches (152 mm) from the corridor wall, above the handrail, shall be permitted for the installation of hand-rub dispensing units.
- SR.6 In anesthetizing locations, which use alcohol-based skin preparations, have implemented effective fire risk reductions measures which include:
- SR.6a. The use of unit dose skin prep solutions
 - SR.6b. Application of skin prep follows manufacture/supplier instructions and warnings.
 - SR.6c. Sterile towels are used to absorb drips and runs during the application and then removed from the anesthetizing location prior to draping
 - SR.6d. Verifying that all of the above has occurred prior to initiating the surgical procedure.
- SR.7 Verify that nonflammable medical gas located outside of an enclosure, in use for patients, does not exceed 300 cubic feet per smoke compartment.

PE.6 EMERGENCY MANAGEMENT SYSTEM

- SR.1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.
- SR.2 The organization shall meet the requirements set forth in NFPA 99, Chapter 12, Emergency Management.

- SR.3 The Emergency Management System shall require that the organization conduct a hazard vulnerability analysis to identify potential emergencies in the organization and the community.
- SR.4 The Emergency Management System shall establish an emergency process to address the potential hazards to the organization and the community. The hospital shall conduct an organization-wide emergency management exercise, including the triage and disposition of patients. The organization-wide emergency management exercises, including the triage and disposition of patients, shall be conducted no less frequently than twice per year
- SR.4a. Emergency management exercises shall test the most threatening hazard(s) identified in the HVA and tax the resources of the organization.
- SR.4b. At least every other emergency management exercise shall be conducted with the community to evaluate surge capacity, the integration of Incident Command and interoperability of communications.
- SR.4c The organization shall formulate an After Action Report of all emergency management exercises to identifying opportunities for improvements and revise its emergency management plan according to the identified opportunities for improvement.
- SR.5 The Emergency Management System processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.
- SR.6 The Emergency Management System shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organizational, community, or regional crisis.
- SR.7 The organization shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

- SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.
- SR.2 The Medical Equipment Management System shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for of demonstration or rental or physician owned equipment.
- SR.3. The Medical Equipment Management System shall address criteria for the selection of equipment.
- SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).
- SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.
- SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.
- SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

PE.8 UTILITY MANAGEMENT SYSTEM

- SR.1 The organization shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for organization-acquired illnesses.
- SR.2 The Utility Management System shall provide for a process to evaluate critical operating components.

- SR.3 The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.
- SR.4 The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).
- SR.5 The Utility Management System shall provide for emergency processes for utility system failures or disruptions.
- SR.6 The Utility Management System shall provide for reliable emergency power sources with appropriate maintenance as required.
- SR.7 The Utility Management System shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.
- SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the organization (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.

Emergency lighting standards shall comply with Section 7.9 of Life Safety Code, 101-2000, and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.
- SR.9 There shall be facilities for emergency gas and water supply.
- SR.10 All relevant utility systems shall be maintained inspected, and, tested,

ORGAN, TISSUE AND EYE PROCUREMENT (TO)

TO.1 PROCESS

- SR.1 The organization shall have a process in place for the procurement of organs, tissue, and eyes. The organization shall have an agreement with at least one tissue bank and one eye bank.

TO.2 ORGAN PROCUREMENT ORGANIZATION (OPO) WRITTEN AGREEMENT

The organization shall have a written agreement an OPO designated under 42 CFR §486. Per SR.1 through SR.5 (below), this agreement shall:

- SR.1 Contain procurement protocols that have been approved by the organization's governing body and medical staff,
- SR.2 Ensure that timely notification is provided to the OPO or a third party designated by the OPO for all individuals whose death is imminent or who have died in the hospital,
- SR.3 Ensure communication of the policy for organ, tissue and eye procurement to all appropriate area of the organization, in addition to any revisions or modifications under a controlled document,
- SR.4 Acknowledge that it is the OPO's responsibility for the determination of medical suitability for organ donation, and, in the absence of alternative arrangements by the organization, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the organization for this purpose.
- SR.5 Ensure, in collaboration with the designated OPO, that the family or each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. If a designated requestor is responsible for initiating this request, this individual must have completed a course offered or approved by the OPO that has been designed in conjunction with the tissue and eye bank

community in the methodology for approaching potential donor families and requesting organ or tissue donation.

- SR.6 Ensure that it works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

TO.3 ALTERNATIVE AGREEMENT

In the event the organization has an alternative agreement with a tissue and/or eye bank, this agreement shall:

- SR.1 Specify the criteria for referral of all individuals who have died in the organization, and,
SR.2 Acknowledge the OPO's responsibility for the determination of medical suitability in lieu of any alternative arrangement with a different tissue and/or eye bank

TO.4 RESPECT FOR PATIENT RIGHTS

The organ, tissue and eye procurement policies, procedures and practices shall demonstrate the respect for individual patient and family rights that reflect their views, religious beliefs and other special circumstances that have been communicated by the patient and/or family to the organization personnel.

TO.5 DOCUMENTATION

Documents and records of organ procurement will be maintained in the manner directed by the OPO.

TO.6 ORGAN TRANSPLANTATION

If the organization performs organ transplantation, the organization shall:

- SR.1 Be a member in the Organ Procurement and Transplantation Network (OPTN), which is established and operated in accordance with section 372 of the Public Service Act (42. U.S.C 274) and abide by its rules,
SR.2 Define the term "organ" as to what transplantation is done. The consistency in terms shall apply to a kidney, liver, heart, lung or pancreas, and,
SR.3 Provide data related to the performance of organ transplantation as requested by the OPTN, the Scientific Registry of Transplant Recipients and the OPO. The organization shall be required to provide this data to CMS as requested by the Secretary.

TO.7 TRANSPLANT CANDIDATES

- SR.1 The organization shall ensure the appropriate candidates for receipt of transplanted organs have been screened, matched and medically cleared prior to receipt of any organs.
SR.2 Candidate information shall be documented, accurate and available at the time of the organ transplantation.
SR.3 Authority for transplantation shall be co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

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DNV ACCREDITATION PROGRAM FREQUENTLY ASKED QUESTIONS JANUARY 11, 2010

Who is DNV Healthcare Inc?

DNV Healthcare Inc. (DNVHC) is an operating company of Det Norske Veritas (DNV). DNVHC has corporate offices in Houston, Texas and Cincinnati, Ohio. DNV is an international, independent, self-supported, tax-paying foundation that has more than 300 offices in over 100 countries and more than 9,000 employees. Established in 1864 in Oslo, Norway, DNV operates 15 offices in the United States and has been in this country since 1898. The corporate purpose of DNV is safeguarding life, property, and the environment. DNV has a worldwide reputation for quality and integrity in certification, standards development and risk management in a wide range of industries, including extensive international healthcare experience. On September 26, 2008 the US Centers for Medicare and Medicaid (CMS) approved DNVHC by granting it deeming authority for hospitals. Any hospital accredited by DNVHC after that date is deemed to be in compliance with the Medicare Conditions of Participation (CoPs).

Who manages DNVHC?

DNVHC is managed by a dedicated group of degreed professionals, each with many years of experience in their respective field of healthcare management, clinical services, health law, ISO certification and engineering. The accreditation management team has extensive healthcare operational experience in the U.S. and understands the dynamics of a complex healthcare organization.

What does NIAHOSM stand for?

NIAHOSM is the acronym for the National Integrated Accreditation for Healthcare Organizations. NIAHOSM is the name of DNVHC's hospital accreditation program. The NIAHOSM standards integrate requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standard for the formation and implementation of the Quality Management System. ISO 9001 is the infrastructure of quality that infiltrates every aspect of your organization – it enables an organization to reach maximum effectiveness and efficiency in its processes that leads to improved outcomes, both clinically and financially. These two sets of standards form the basis of DNVHC's revolutionary Integrated Accreditation concept in NIAHOSM.

Does the hospital have to be ISO compliant before it can receive DNV accreditation?

No. You can be accredited by DNV immediately after the first survey without being in compliance with ISO 9001. In fact, unless the hospital is currently involved with ISO, it is not expected to be in ISO 9001 compliance at the time of the first survey. The hospital has three years to become compliant with ISO 9001 after the first DNV survey. After submitting an acceptable Corrective Action Plan, if needed, and upon approval by the Accreditation Committee, DNV's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is

determined by CMS. The hospital then has up to three years to become ISO 9001 compliant. The first survey has two goals- conduct a CMS deemed-status accreditation survey for Medicare certification and introduce the hospital to the ISO 9001 Standard. The second year accreditation survey includes an ISO 9001 preassessment. These two activities are conducted by one survey team during the initial survey. It should be noted that most hospitals currently accredited by DNV have become ISO 9001 compliant without adding any additional staff.

Can the hospital immediately switch its accreditation to DNVHC without interruption in Medicare reimbursement?

Yes. If a hospital wants to switch its accreditation to DNVHC, it can notify its current accreditation organization (AO) as soon as it has made its decision. Hopefully, the hospital and the AO will work out a plan for an orderly transition. If the hospital and AO cannot agree and the AO immediately withdraws its accreditation, the hospital's Medicare provider agreement is not affected. The current AO will notify the CMS Central Office (CO) and applicable Regional Office (RO) that it has withdrawn its accreditation and the effective date.

If the hospital's termination by one AO is concurrent with the new recommendation for accredited, deemed status by DNVHC, then it may remain under DNVHC rather than State Survey Agency (SA) jurisdiction.

If the hospital's termination by its current AO is not concurrent with a new recommendation for accredited, deemed status by DNVHC, the hospital is placed under SA jurisdiction until such time as a new recommendation for accredited, deemed status by DNVHC is received and approved by the CMS CO and appropriate RO. The hospital's accredited, deemed status is then reestablished and the hospital is placed under DNVHC for ongoing monitoring and oversight. During the transition from the hospital's current AO to DNVHC or, if the transition is not concurrent, from the hospital's current AO to the SA then to DNVHC, **there is no interruption in the Medicare provider agreement, and thus, no break in Medicare reimbursement.**

What is ISO 9001?

The ISO 9001 Standard was first published in 1987 and was recently revised in 2008 to address the issues encountered by facilities in the service industries, including healthcare. ISO changes the standards no more frequently than every six years. This allows the hospitals to stabilize their processes and ensure effectiveness instead of forcing the hospitals to chase a constantly moving target of changing standards.

How is the NIAHOSM survey performed and when does DNVHC's accreditation become effective in terms of Medicare and Medicaid reimbursement?

The NIAHOSM and ISO surveys are done together through Tracer Methodology as well as staff and patient interviews. While surveying the hospital to the CoP criteria, DNVHC surveyors also ensure the applicability of the ISO 9001 standard. Tracer Methodology has been a staple of ISO 9001 surveys since ISO 9001's inception in 1987. All areas of the hospital are surveyed, both clinical and non-clinical. Tracer Methodology is a tool to identify and document effective processes.

DNVHC surveyors are recruited from the hospital and related sectors and trained extensively in the classroom and in the field by DNV in NIAHOSM and the ISO 9001 Standard.

There are always at least two surveyors on site (two for small hospitals and three to five for larger hospitals). There will always be either a physician or registered nurse and a physical environment (PE) specialist on site. A Generalist will also be a part of the team for larger hospitals. The PE specialist is a fully functioning team member and will be there throughout the entire survey. All teams include surveyors with extensive healthcare clinical and management background.

Once the survey is completed the hospital will receive a preliminary report from the survey team. The hospital will receive a final report from DNVHC within ten days. The hospital will then have ten days to submit its Corrective Action Plan with timelines for implementation. Once the Corrective Action Plan has been approved, the documentation is submitted to the Accreditation Committee for the final accreditation decision. Upon approval by the Accreditation Committee, DNV's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is determined by CMS.

How long does a hospital have to become compliant with the ISO 9001 Standard?

The NIAHOSM standards allow up to three years from the initial NIAHOSM survey to become ISO 9001 compliant. Our experience shows, however, hospitals can begin to realize positive outcomes in the first year.

If a hospital is currently accredited by TJC or AOA or has received a State survey, it is basically 65-75% of the way to ISO 9001 compliance. The hospitals we have surveyed that have implemented ISO have taken 3-6 months for ISO implementations. The schedule we follow is outlined below. These are **annual** on-site visits.

- Year One – NIAHOSM Accreditation and Introduction to ISO 9001
- Year Two – NIAHOSM Accreditation and ISO 9001 Pre-assessment Survey (The pre-assessment is an analysis to show the hospital where it is currently compliant with ISO and any gaps that need to be addressed to become ISO 9001 compliant.)
- Year Three- NIAHOSM Accreditation and Stage One ISO 9001 Surveys (Stage One is designed to confirm hospital readiness for an ISO 9001 compliance/certification audit.)

Year Four- NIAHOSM Accreditation and ISO 9001 Compliance/Certification Audit.

Years Five- NIAHOSM Accreditation and ISO 9001 periodic audit.

Year Six- NIAHOSM Accreditation and ISO 9001 periodic audit.

The first contract for accreditation services is a three year contract (see above) in order to confirm the hospital's readiness for an ISO 9001 Compliance/Certification Audit, unless the hospital is already certified to ISO 9001. Existing hospital certification to ISO 9001 is typically not the case. ISO 9001 compliance/certification is determined in Year Four. Hospitals that want to move forward with the ISO 9001 process at an accelerated rate will be able to work with DNV to develop a strategy that meets their particular needs and allows them to achieve their objectives within an agreed time frame.

The next and subsequent three-year contracts would be identical to Years Four, Five and Six.

In terms of CMS deeming authority, DNVHC can accredit any part of the organization that is included under the hospital CCN Number (formerly Medicare Provider Number). However, even if some parts of the organization are not surveyed for accreditation, these functions can still be audited for compliance/certification to ISO 9001. DNVHC encourages this because it drives consistency and best practices throughout the organization.

How often do the NIAHOSM standards change?

There are two types of changes to the NIAHOSM standards - mandatory and discretionary:

Mandatory- DNVHC is required to change NIAHOSM standards to conform to any CMS change in the Medicare CoPs. DNVHC is required to implement these changes in NIAHOSM standards within thirty (30) days of the new CoP effective date.

Discretionary- DNVHC may add, remove or amend any NIAHOSM standard that is not required by the CoPs. Discretionary changes will clarify existing standards and incorporate practices, principles and processes that will enhance the NIAHOSM accreditation program. Such changes will be implemented only if they can be expected to improve the overall quality and safety of patient care. Discretionary changes will occur through a dynamic review process that will involve input from the field, comments from applicable agencies and organizations and review by the DNVHC accreditation management team. Any discretionary change to the NIAHOSM standards must be approved by the DNVHC Standards and Appeals Board (SAB). The SAB is comprised of representatives active in medicine, nursing and hospital management. Since ISO 9001 is already designed to encourage and accommodate contemporary best practices, discretionary changes should be infrequent.

How long have hospitals been surveyed to the NIAHOSM standards?

The NIAHOSM application process to CMS took approximately four years. CMS requires that an applicant organization for deeming authority continue its survey program throughout the submission process. DNVHC worked with many hospitals throughout the United States to develop standards, field train surveyors and submit to the entire NIAHOSM hospital program. This participation has occurred despite the need to maintain TJC accreditation (or other) accreditation because these hospitals were looking for an alternative accreditation. As a result the NIAHOSM standards and survey process have been in place continuously for five years.

What are the training and qualifications of DNVHC surveyors?

There are three classifications of DNVHC surveyors: Clinical Surveyors, Generalist Surveyors, and Physical Environment (PE) Specialists. The Clinical Surveyor is either a physician or a registered nurse; the Generalist Surveyors may have a clinical (not a physician or registered nurse) or nonclinical hospital background. The PE Specialists come with a facilities and safety background.

All DNVHC surveyors must successfully complete NIAHOSM Surveyor didactic training and separate ISO 9001 Lead Auditor didactic training. The PE Specialists receive further training in the NFPA Life Safety

Code. Following the classroom, each surveyor completes a sufficient number of surveys in a student role until their trainer validates that the surveyor is ready to perform as a Team Member.

In addition to the surveyor background and competency, all surveyors are evaluated in terms of their interpersonal skills. Surveyors must possess sufficient interpersonal skills to translate into a collegial, non-confrontational survey. The surveyors clearly understand that anything less is unacceptable.

All surveyors must complete 45 hours of continuing education in their discipline within every three year period. Additionally all surveyors must participate in annual surveyor training as well as other courses offered throughout the year by DNV and DNVHC staff.

The NIAHOSM standards require either ISO Certification or ISO Compliance. What is the difference between ISO Certification and ISO Compliance?

The NIAHOSM standards require that a hospital become **Compliant** with ISO 9001 within three years of the first NIAHOSM survey but **Certification** to ISO 9001 is an option that the hospital may select.

Compliance means that the hospital has implemented all requirements of ISO 9001 and is **compliant** with the ISO 9001 standard. The hospital will receive **one** Certificate for NIAHOSM accreditation that includes confirmation that the hospital is also compliant with the ISO 9001 standards.

In a competitive marketplace, a hospital may want to further publicize its ISO compliance by displaying the separate internationally-recognized ISO 9001 certificate. When a hospital is ISO certified, it will receive **two** certificates, one for NIAHOSM Accreditation and another certificate for ISO 9001 Certification.

Certification involves significant additional DNVHC documentation apart from CMS requirements. Issuance of a separate ISO certificate requires this additional documentation to be prepared by DNVHC and sent to a separate ISO Certification Body to provide the international ISO recognition. This additional work by DNVHC requires an additional charge to the hospital of \$3,500. If Certification is requested by the hospital, the ISO Certification Body will determine the number of survey days required for the survey. If Compliance only is selected, DNVHC will have more latitude in determining the number of survey days. Since survey days drive the cost, DNVHC would have more latitude in determining costs.

In either case, the hospital will have to be fully compliant with the ISO 9001 standards within three years. There is no difference in meeting the ISO 9001 requirements whether it is a Compliance Survey or a Certification Survey. The only difference is in the cost of the internationally-recognized ISO certificate. It is a decision for the hospital to make based on its market.

Does DNVHC provide any resources for ISO 9001 and/or NIAHOSM implementation?

Yes. DNVHC offers an ISO 9001/NIAHOSM Implementation course. This one-week course is offered at various times throughout the country. Check www.dnvaccreditation.com for dates and fees. This course can also be offered on-site to an individual organization for a fee and expenses. Call the DNVHC toll-free number (866-523-6842) for more information.

DNVHC also publishes a roster of consultants who have successfully completed the DNVHC NIAHOSM Accreditation Standards course and the specific ISO 9001 Lead Auditor course approved by DNVHC for healthcare organizations.

DNVHC maintains and publishes this roster solely as a convenience to the healthcare public for organizations that are interested in pursuing or maintaining DNVHC accreditation and/or becoming ISO 9001 compliant. DNVHC has no financial relationship with these persons when they are providing these services. DNVHC does not endorse, approve or recommend any person listed on the roster.

The roster is available on website www.dnvaccreditation.com under the Resources tab.

What other training does DNVHC offer to the hospital field?

DNVHC offers free 90 minute webinars from time to time. Additionally, DNVHC offers full-day and week-long training programs in NIAHOSM and ISO 9001 in locations across the country as demand requires. There is a charge for these programs. See www.dnvaccreditation.com for information when these webinars and programs are offered.

DNVHC is also willing to come on-site to individual organizations for a fee and expenses. Call DNVHC for more information.

DNVHC also has a unique program for its customers. DNVHC will train one individual in the organization to the NIAHOSM and ISO 9001 Standards. DNVHC does not pay these individuals a salary or reimburse their expenses during training, nor do we charge for the training or related literature and training tools. The ISO 9001 Lead Auditor training involves 5 days and the NIAHOSM training takes 4 days, both weeks in our Cincinnati offices.

The hospital must agree to allow the staff member to survey up to two times per year (if needed by DNVHC) as a fully qualified surveyor and a full member of the survey team – obviously not in their market area. It typically takes 2-3 surveys after training for the staff member to become comfortable with being a full team member. Once the staff member successfully completes the didactic training (usually in Cincinnati, Houston or Atlanta), all travel expenses of surveying are paid by DNVHC and salary remains the hospital's responsibility.

DNVHC's training and use of hospital-based surveyors is based on availability and need.

These staff members would receive all changes and documentation that any other surveyor for DNVHC receives and will always be current with CMS changes in requirements as well as NIAHOSM and ISO 9001 changes or modifications and survey nuances. While the hospital will receive all standards updates, these staff members would be on all surveyor conference calls,

emails, or other training and/or communication. This is DNVHC's commitment to a totally transparent survey process.

If a hospital changes its mind about DNV accreditation, can the hospital terminate the contract?

Contracts are quoted in multiyear cycles to maintain accreditation and ISO continuity. If a hospital does not want to continue DNVHC accreditation, it may terminate its contract at any time with a 60-day written notice.

How do the number of findings during a survey affect the hospital's accreditation decision?

The number of findings during a survey has no effect on accreditation. There is no tipping point of findings such that one more finding will lead to non-accreditation. Continual improvement and adherence to the Corrective Action Plan is the key to DNVHC Accreditation.

(More detailed information pertaining to Nonconformities can be obtained in the *Accreditation Process* document that can be downloaded at no charge on the www.dnvaccreditation.com website.)

Do the NIAHOSM standards contain patient safety goals?

DNVHC supports the initiatives that hospitals have developed and implemented to guide safe patient care practices. We also support and foster innovations through development of hospital best practices, but clearly understand that some practices do not suit all organizations. DNVHC does not dismiss the notion that patient safety goals can be effective and many organizations may want to consider these "goals" in place of their current practices. However, we also realize that there are different avenues for achieving positive patient safety outcomes and the hospitals know their patient populations and resources best. The decision-makers in each individual hospital are certainly well-trained, qualified, and best equipped address these issues. DNVHC will look at the outcomes to validate problem resolution.

DNVHC has two major goals – to assess compliance and educate hospitals in best practices. Hospitals can use innovation to develop new methods for producing positive results, but not by DNVHC forcing one practice over another when good outcomes are being achieved. At the same time, we hold hospitals accountable to ensure that processes are planned, managed, measured, documented and continually improved.

Does the DNV parent company in Oslo make accreditation decisions?

No. All accreditation decisions are made by DNVHC in the U.S. If a hospital is dissatisfied with an accreditation decision, it may appeal to the Standards and Appeals Board (SAB). The SAB is an independent body chartered by the DNVHC board of directors to hear accreditation appeals. All SAB members are Americans. They have extensive training and experience in the U.S. healthcare system and are eminently qualified in their respective fields of medicine, nursing and hospital management. The decision of the SAB is final.

What is the cost of purchasing the NIAHOSM standards?

- ♦ There is no charge for the NIAHOSM Standards, Interpretive Guidelines, or Accreditation Process for non-commercial use. These can all be downloaded at www.dnvaccreditation.com.
- ♦ The ISO 9001 standards can be purchased at www.iso.ch or www.asq.com.
- ♦ Another excellent source for ISO in healthcare is a publication from Australia. It may be purchased at <http://www.saiglobal.com/shop/Script/Details.asp?DocN=AS318210814901>. It is the Australia Standards Guide and the purchase information is: HB 90.8-2000: Healthcare Services – Guide to ISO 9001.

What are the costs associated with a NIAHOSM accreditation?

The cost of the survey is based on the number of surveyors and the length of the survey. Survey team size and number of survey days are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census (ADC) and **number of FTEs**
- Complexity of services offered, including outpatient services
- Type of survey to be conducted
- Whether the facility has special care units or off-site clinics or locations and the distance from the main campus

Contracts are typically for three years. However, a hospital can terminate its contract at any time with a 60-day written notice. The attached Appendix contains several scenarios that outline approximate costs based on the size and complexity of the hospital. Please understand that the number of off-sites and the distance from the hospital may have an impact on the number of surveyor days. For purposes of these scenarios, 3-4 off-sites are assumed to be present and within 20 miles of the hospital.

It is important to remember that the hospital will receive an on-site visit **every year** (e.g., in three years the hospital would have **three on-site surveys** instead of one survey every three years). Current DNVHC hospitals view this as a significant benefit.

Please note the higher number of on-site survey days the hospital will receive with DNVHC as compared to the number of on-site survey days that the hospital has been receiving in its current accreditation program. **It is the increase in survey days that will reduce (and in most cases eliminate) the ramp-up costs that the hospital currently incurs.**

Quotations for annual surveys include all fees and expenses. There is no charge for the NIAHOSM Requirements and Interpretive Guidelines for non-commercial use and you may contact us for standards interpretation or other questions by email or telephone on an unlimited basis at no charge. There are no hidden charges.

The attached Appendix depicts a fee schedule for various sized hospitals. The schedules include the time and fee structure for the first 3-year cycle and subsequent 3-year cycles, based on average daily census (ADC) and number of FTEs. **The number of FTEs is the single most important factor when determining costs. It is essential that the hospital FTE count on the DNVHC Application for Accreditation is completely accurate.**

Are there indirect costs associated with DNVHC accreditation?

No. Quotations include all fees and expenses. There are no annual charges, consulting costs, additional staff or other expenses necessary to maintain the NIAHOSM accreditation program or the ISO 9001 quality management system. TJC hospitals can spend thousands of dollars each with TJC's affiliate, Joint Commission Resources (JCR) preparing for a TJC survey. This does not count the indirect internal costs hospitals may spend ramping up for a TJC survey. JCR sells consulting and publications to hospitals to help them prepare and maintain TJC accreditation and keep abreast of ever-changing TJC standards. JCR had revenue in excess of \$48 million in 2007 (latest available). **There are no ramp-up or maintenance costs for DNVHC accreditation.** Hospitals are just using existing staff to do different things. **There is no need to incur the expense of preparing for and undergoing "mock surveys" to prepare for DNVHC accreditation.** For many hospitals, this can equal the cost of actual accreditation.

Are the costs computed differently for Hospital Systems?

Yes. An economy of scale is built into the ISO formula that determines the number of survey days. A Hospital System (HS) can be surveyed in one of two ways. The HS can implement one Quality Management System (QMS) using the principles of ISO 9001, or the individual hospitals in the HS can each implement their own QMS.

If the HS selects a single QMS the corporate office would oversee the QMS and the principles would reach through all the HS hospitals, assuring consistency and best practice across all hospitals. Because it is a single QMS, the ISO table dictating survey days compresses as the number of employees increases; therefore, the cost of the contract is significantly less if the HS implements a single Quality Management across the organization because the survey days are reduced.

If the HS decides to have individual Quality Management Systems, DNVHC would be required to validate compliance with each individual QMS within the system and that involves many more days, resulting in higher costs.

DNVHC recommends that the HS select the single QMS to maximize the opportunity to bring consistency and known best practice across the organization. In either scenario, all hospitals in the HS would receive an on-site survey each year.

Any other questions? Contact:

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Appendix A: Time and Fee Schedule Examples

The following examples are for reference only; actual costs will be based on the hospital's size and complexity as outlined in the individual hospital's Application for Accreditation.

Ex.	Average Daily Census (ADC)	Employees (FTEs)	Average Survey Days on Site Each Year	Average Number of Surveyors On Annual Survey	Average Surveyor Days On-Site Each Year	Average Annual Cost	Hospital's Current Accreditation Fees (to be completed by hospital)		
							Number of Days On Site In 3-Year Period	Direct Cost (annual fee + survey every 3 years)	Indirect Costs (consulting, standards and publications, mock surveys)
1	10	85	1 - 2	2	2.5	\$7,800			
2	30	210	1.5 - 2	2	3.5	\$11,800			
3	75	375	2	2-3	4.5	\$15,100			
4	125	625	2 - 2.5	2-3	5	\$17,000			
5	180	900	2.5 - 3	2-3	6.5	\$21,000			
6	250	1250	3	2-3	7	\$23,100			
7	350	1760	3 - 3.5	3	8	\$27,000			
8	450	2250	3 - 3.5	3-4	9	\$29,500			
9	650	3250	3 - 4	3-4	10	\$33,000			

The above DNVHC fees are all-inclusive. These fees include all travel expenses, NIAHOSM standards and related documents and include an on-site visit every year.

ATTACHMENT 8

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

<p>Objective 2.1</p> <p>Measure:</p>	<p>Issue licenses within three working days of a completed application by June 30, 2011.</p> <p>Percentage of licenses issued within three work days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Review 100 percent of all applications within seven work days of receipt. 2. Process 100 percent of all deficiency documents within five work days of receipt. 3. Make a licensing decision within three work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. <ul style="list-style-type: none"> • Pharmacists • Intern pharmacists • Pharmacy technicians • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Designated Representatives (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors • Sterile Compounders 5. Withdrawn licenses to applicants not meeting board requirements. 6. Deny applications to those who do not meet California standards. 7. Respond to e-mail status requests and inquiries to designated e-mail addresses. 8. Respond to telephone status request and inquiries.
<p>Objective 2.2</p> <p>Measure:</p>	<p>Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.</p> <p>Percentage of revenue cashiered application within 2 working days.</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Cashier application fees. 2. Cashier renewal fees. 3. Cashier citations with fines. 4. Cashier probation and cost recovery fees. 5. Cashier request for information/license verification fees. 6. Cashier fingerprint fees.

<p>Objective 2.3</p> <p>Measure:</p>	<p>Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.</p> <p>Percentage of licensing records changes within five working days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Make address and name changes. 2. Process off-site storage applications. 3. Transfer intern hours to other states
<p>Objective 2.4</p> <p>Measure:</p>	<p>Implement at least 25 changes to improve licensing decisions by June 30, 2011.</p> <p>Number of implemented changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. 2. Evaluate the drug distribution system of clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. 7. Review requirements for qualifications of pharmacy technicians with stakeholders. 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 BreZE system will take its place. 9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards. 10. Implement new test administration requirements for the CPJE. 11. Participate in ACPE reviews of California Schools of Pharmacy. 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training. 13. Convene Committee to evaluate drug distribution within hospitals. 14. Improve reporting of and accounting for intern hours. 15. Participate in initiatives to increase the number of pharmacists in California to meet demand. 16. Assess the operations of specialty pharmacy services. 17. Encourage use of technology where it benefits the public. 18. Secure the implementation of e-prescribing in California by the earliest possible date. 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic. 20. Automate fingerprint background results with the Department of Justice. 21. Evaluate pharmacy technician application process to identify areas for improvement. 22. Implement fingerprint requirement for Pharmacist renewal. 23. Evaluate licensing requirements for businesses seeking licensure under common ownership.

ATTACHMENT 9



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

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

DATE: June 16, 2010

LOCATION: Bonderson Building
901 P Street, Hearing Room 102
Sacramento, CA 95814

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Public Member, Chair
Ramón Castellblanch, Public Member
Tappan Zee, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Ryan Brooks, Public Member
Deborah Veale, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

Chair Lippe called the meeting to order at 2:08 p.m.

1. **Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – New University of New England School of Pharmacy of Portland, Maine**

Chair Lippe provided that the University of New England School of Pharmacy is requesting board recognition of its program for purposes of issuing California intern pharmacist licenses to students attending their program, but who may spend some time and work in CA. He stated that precandidate status is a

provisional status awarded to a new school of pharmacy; however it is not "approved" status.

Executive Officer Virginia Herold provided that typically pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future. In this case, she advised that the university may achieve candidate status by the end of June 2010.

No public comment was provided.

MOTION: Recommend to the board recognition of the University of New England, College of Pharmacy, Portland Maine.

M/S: Lippe/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

2. Discussion of Proposed Changes to the Intern Hours Requirements for California

Chair Lippe provided that under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California.

Chair Lippe provided that additionally board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. He stated that the remaining 600 hours must be earned under the supervision of a pharmacist and must be substantially related to the practice of pharmacy, but are not required to be earned specifically within a pharmacy. Chair Lippe indicated that California pharmacy students typically earn these 600 "discretionary" hours for school-related experiential training (such as a clinical clerkship).

Chair Lippe provided that recently, board staff received a new proposal to modify the intern hour requirements. He stated that the proposal requests that the board change the current requirements to specify a minimum of 600 hours of pharmacy experience earned under the supervision of a pharmacist in a pharmacy, and to allow that the remaining 900 intern hours be accrued within a school of pharmacy. Chair Lippe indicated that the proposal states that UCSF's current curriculum includes more than 1,000 hours of advanced pharmacy practice.

Dr. Ramón Castellblanch asked how this change for UCSF would impact other schools of pharmacy.

Assistant Executive Officer Anne Sodergren provided that several similar proposals have been brought before the committee over the past several years. She advised that this proposal would require a regulatory change.

Chair Lippe expressed concern that decreasing the hour requirement may have a detrimental impact to an intern's experience in the field.

Ms. Sodergren provided that the committee has historically denied similar proposals. She stated that the proposal has been presented before the committee because the practice of pharmacy is changing and the pharmacist's role is evolving. Ms. Sodergren advised that there is no substitute for practice hours.

Dr. Castellblanch questioned why a representative from UCSF was not present to personally make this request.

Ms. Herold indicated that UCSF was notified that the proposal would be presented to the committee. She explained that interns are struggling to achieve positions in order to obtain the experience hours due to the declining economy. Ms. Herold stated that the board may choose to consider input from other groups including pharmacy schools and pharmacists on the minimum hours that would satisfy this requirement.

Chair Lippe suggested that the board consider two different types of licensees to reflect variance in training emphasis inside the pharmacy.

Tappan Zee suggested that the committee recommend that the board consider that the hour requirements be flipped.

Public Comment

William Young provided that many pharmacists feel that recent graduates do not have sufficient experience when entering the profession. He stated that he believes the shift would be detrimental. Mr. Young encouraged the board not to adopt this proposal.

Dr. Steve Gray, representing Kaiser Permanente, provided that without pharmacy experience, graduates are not able to recognize and identify the drugs. He indicated that the National Association of Boards of Pharmacy (NABP) is amending its policy to require an increase to 1700 intern hours of experience prior to licensure.

Robert Ratcliff, Supervising Inspector, indicated that from an enforcement perspective, granting this change would be detrimental to the public. He recommended that the experience hour requirements be increased.

Dr. Gray provided that the American Society of Health-System Pharmacists (ASHP) has reaffirmed its position that by 2020, pharmacist licensure will require a mandatory one-year postgraduate residency prior to licensure. He advised that other associations are also moving towards this policy.

There was no additional committee discussion or public comment.

3. Review of Data Describing the Board of Pharmacy's Audits of Continuing Education Earned by Pharmacists as a Condition of Renewal

Chair Lippe provided that pharmacists are required to complete 30 hours of continuing education as a condition of license renewal. He indicated that these CE hours must be earned within the two years their license was last renewed. Chair Lippe explained that at the time of renewal, every pharmacist must certify under penalty of perjury that he or she has completed the 30 units.

Chair Lippe provided that the board periodically audits a few pharmacists each month to determine their compliance with this requirement. He advised that if they are unable to provide 30 hours of CE for the renewal period, they are directed to immediately provide proof of completion of additional CE now (earned outside the renewal period, but to bring them into compliance) and then are cited and fined.

Chair Lippe provided that if the pharmacist does not come into compliance, Business and Professions Code section 4231 allows the board to convert the renewal to an inactive license -- which means the individual cannot work as a pharmacist in California.

Chair Lippe provided that the results of recent board audits indicates that 16 percent of those audited could not provide proof of completion of continuing education credits earned during the last renewal period. He stated that of these, 5 (2 percent) ended up having their licenses converted to inactive status.

Ms. Herold provided that failed CE audits have dropped from 25% to 16%. She advised that both the pharmacist and the employer will be cited and fined if it is found that the pharmacist has been working with an inactive license.

The committee further discussed the CE process. It was suggested that pharmacists submit proof to document completed CE. Concern was expressed that this process will significantly impact work load.

Public Comment

Dr. Steve Gray suggested that the board may want to consider the establishment of CE categories relevant to the practice issues before the profession today. He

stated that targeted categories may make the CE requirement more meaningful and encourage compliance.

It was the consensus of the committee to recommend that the full board discuss the topic of targeted CE. Direction was given to staff to establish parameters in this area.

There was no additional committee discussion or public comment.

4. Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include “Self-Query” Reports From the Healthcare Integrity and Protection Data Bank (HIPDB)

Ms. Herold provided that board staff proposes a change to the application requirements to also include a “self-query” report as part of the application process. She stated that requiring such a search will ensure that the board has all relevant information when making a licensing decision and does not inadvertently issue a pharmacist or intern license to an individual that has been disciplined in another state unless, after review of the information, it determines that such an issuance is consistent with the board’s consumer protection mandate.

Ms. Sodergren indicated that a “self-query” costs \$16.00 per report. She stated that if the state was required to run this report, it would cost \$4.75 per report for each state the applicant was licensed with.

No public comment was provided.

MOTION: Recommend that the board take action on this item to adopt the “self-query” report requirement.

M/S: Zee/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

5. Emergency and Disaster Response Planning Update

Chair Lippe provided that in 2007, the board developed and released an emergency response policy, pursuant to California Business and Professions Code section 4062 to waive statutory requirements to benefit public safety in response to a declared emergency or disaster. He indicated that in 2009, the section was amended to add subdivision (c) to provide for use of temporary facilities during declared emergencies.

Chair Lippe provided that at the October 2009 Board Meeting, the board voted that in situations following a declared emergency where the board cannot convene a meeting timely, that the board delegates its authority to waive statutory requirements to benefit public safety in response to a declared emergency or disaster to a committee of three board members via teleconference.

Chair Lippe read the following motion approved by the board.

MOTION: In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., e-mail), or by other means of communication to exercise the powers delegated to full board pursuant to Business and Professions Code section 4062.

Chair Lippe provided that the executive officer was recently asked the following questions by the California Department of Public Health:

- How will the board know when to rescind its emergency suspension of requirements under the emergency provisions once the emergency has ended?
- What is the trigger for the emergency to be dissipated and have licensees return to practices?
- Who initiates and when does it go into place?

Chair Lippe reviewed the following response provided by the executive officer:

There is no definitive answer. Often there is a point where either the Governor or the Office of Emergency Services makes a statement that the emergency is over. The California Department of Public Health, I would suspect, would also be a likely agency to note when the emergency has dissipated. At some point, business and patients return to normal. This is the point when the board would advise entities to return normal business practices. In the limited instances where the board used its emergency policy (several years ago during CA's wildfires), we did not need to issue notice about the end of the emergency. Things returned to normal on their own.

Chair Lippe provided that the board may wish to discuss and amplify this response, and develop its policy about criteria for ending the emergency authorization.

Dr. Castellblanch recommended that the special committee would adjourn to signal the end of the emergency authorization. He encouraged input from the board's counsel on this issue.

It was the consensus of the committee to discuss this item at the July 2010 Board Meeting and to establish procedures for mobile pharmacies.

No public comment was provided.

6. Competency Committee Report

Chair Lippe highlighted the following items.

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

The board instituted a quality assurance review of the CPJE effective April 1, 2010. This process is done periodically to ensure the reliability of the examination. As of the date of this report, approximately half of the candidates required to complete the quality assurance review have taken the CPJE. The board intended to complete this review and release examination results in June 2010. As soon as the required numbers of candidates have taken the CPJE, the board will release the results.

Job Analysis and Content Outline for the CPJE

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. To complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. The information learned from 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 has worked on revising its content outline and the completed work was presented to the board at the April 2010 board meeting. During this meeting, the board reviewed and approved the new content outline. The Competency Committee will begin working with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Competency Committee Meetings

Competency Committee Workgroups have met three times during 2010 to develop the CPJE. Both workgroups will meet together at their annual meeting in August to continue examination development as well as incorporate the new

content outline and ensure implementation for examinations administered after April 1, 2011.

No public comment was provided.

7. **Review of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies**

Chair Lippe provided that the 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. He stated that these specialized pharmacies may be either hospital pharmacies or community pharmacies. Chair Lippe advised that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. He indicated that this is the only category of board licensure that requires annual inspections as a condition of renewal.

Chair Lippe provided that currently the board has 243 such licensed facilities in California, and 93 nonresident pharmacies with such permits.

Chair Lippe provided that 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.

Chair Lippe provided that currently there are two accreditation agencies approved by the board: 1) Accreditation Commission for Health Care, Inc (ACHC), and 2) Community Health Accreditation Program (CHAP). He stated that at the April 2010 Board Meeting, the board extended the accreditation of these two agencies for one year while the board prepares a detailed review.

Chair Lippe provided that 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. He indicated that recently the board modified its regulations for pharmacies that compound medication. Chair Lippe explained that included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. He stated that these regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, will take effect July 6, 2010. (The board also directed an

additional six months of “educational” enforcement for the new requirements to facilitate compliance.)

Chair Lippe provided that since 2003 when both agencies were approved by the board, board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. He stated that in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. Chair Lippe indicated that 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. He advised that both agencies were last reviewed by the board in 2006.

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditator'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.

Chair Lippe provided that at the April 2010 Board Meeting board staff were directed to (1) review and assess the three accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding pharmacies, (2) bring staff's report to a future Licensing Committee Meeting (the next meeting is scheduled for June 16, 2010), and (3) bring the committee's recommendations to the board for action at a future meeting.

Chair Lippe provided that staff believes that a meaningful review of the two agencies and a third accreditation agency seeking board approval involves the agencies' incorporation of the new sterile injectable compounding requirements and ability to accredit against these standards into their accreditation inspections. He indicated that at the current time, the board has not initiated this review of the

accreditation standards (although all three agencies have been advised of the modified requirements).

Chair Lippe provided that the following three agencies are requesting board approval as accrediting agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)
2. Community Health Accreditation Program (CHAP)
3. New -- Det Norske Veritas (DNV)

Janice Dang, Supervising Inspector, provided a review of each agency to assess a pharmacy's ability to meet the board's requirements for sterile injectable compounding pharmacies. She highlighted both the current requirements and the new requirements for each agency.

Ms. Dang expressed concern that the surveyors for each agency may not be adequately familiar with California modified pharmacy law. She indicated that the agencies may not be compliant with new compounding laws effective July 2010.

Ms. Herold indicated that Ms. Dang's full report will be brought to the full board at the July 2010 Board Meeting.

Patrick Horine, representing Det Norske Veritas (DNV) Healthcare Inc., provided an overview of the DNV accreditation program, National Integrated Accreditation for Healthcare Organizations (NIAHO). He indicated that NIAHO standards integrate requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standard for the formation and implementation of the Quality Management System. Mr. Horine stated that the model's standards are consistent with California pharmacy law.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, recommended that the board invite the Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations, to present their processes in this area at a future meeting.

There was no additional committee discussion or public comment.

8. Licensing Statistics

Chair Lippe provided that the board continues to experience significant increases in applications, most notably in pharmacy technicians. He reviewed the following significant increases from July 1, 2009 through May 31, 2010.

Applications Received:

Pharmacy Technicians	10%
Sterile Compounding	13%
Wholesalers	21%

Licenses Issued:

Pharmacy Technicians	25%
Wholesalers	21%

Ms. Sodergren advised that the statistics reflect the growth from this fiscal year compared to last fiscal year. She stated that board staff have been notified that the applicant tracking reporting system that generates the data has experienced an error. Ms. Sodergren indicated that a new revised report including a three year comparison will be provided at the July 2010 Board Meeting.

There was no additional committee discussion. No public comment was provided.

9. Update of the Licensing Committee's Strategic Plan for 2010-2011

Ms. Herold provided that board staff strive to manage its operations by the strategic plan. She stated that all activities undertaken by the board are reported in the plan -- in the component committee reports provided quarterly to the board (in the board packets).

Ms. Herold provided that the Licensing Unit managers reviewed the plan in advance of this meeting and are recommending inclusion of the following tasks:

- Initiate changes to improve internal processing of application process
- Initiate internal and external processing of pharmacy technician applications
- Implement Fingerprint Requirement for Pharmacist Renewal. (Regulation recently approved by OAL.)
- Initiate internal and external processing of site licensing applications

The committee discussed the organization of the strategic plan. Clarification on the included objectives was requested.

10. Public Comment for Items Not on the Agenda

William Young provided comment on the prevalence of perjury on the continuing education (CE) certification on the licensure renewal. He recommended that the board consider its CE methodology and tracking as one of its initiatives.

The committee discussed the submission of CE certificates as proof of completion of the CE requirement. Consideration was given to the increased workload impact this would have.

The meeting was adjourned at 4:07 p.m.

ATTACHMENT 10

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	185	132	131	133	87	125	29	105	161	195	343	696	2322
Pharmacist (initial licensing applications)	279	286	161	155	125	69	93	90	79	51	23	39	1450
Intern pharmacist	61	479	328	310	57	68	27	81	158	99	106	93	1867
Pharmacy technician	962	897	1035	1023	685	1022	202	845	1256	1005	1089	1145	11166
Pharmacy	29	21	30**	26	18	25	19	26	25	100	101	29	419
Sterile Compounding	6	2	1	5	2	1	2	25	7	6	10	4	71
Clinics	6	4	13	5	3	8	5	8	2	10	19	5	88
Hospitals	0	0	3	2	0	0	1	0	0	16	14	0	36
Nonresident Pharmacy	3	4	3	6	5	1	8	3	20	14	9	5	81
Licensed Correctional Facility	0	0	0	0	0	0	2	0	0	0	0	0	2
Hypodermic Needle and Syringes	1	3	2	0	2	2	2	0	0	0	0	0	12
Nonresident Wholesalers	6	15	6	8	5	13	2	2	9	18	25	4	113
Wholesalers	5	7	4	14	5	6	6	1	7	10	19	6	90
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives	34	57	35	75	36	33	22	45	47	36	42	40	502
Issued													
Pharmacist	243	308	139	189	94	101	87	93	53	83	21	10	1421
Intern pharmacist	39	277	323	476	102	119	44	19	73	184	109	69	1834
Pharmacy technician	751	788	764	722	416	1407	889	704	1017	1016	1067	1955	11496
Pharmacy	35	24	36	24	7	12	25	13	33	33	16	19	277
Sterile Compounding	9	2	7	1	0	0	0	2	1	4	4	8	38
Clinics	5	4	11	1	10	4	8	0	9	3	1	6	62
Hospitals	6	1	5	2	0	0	4	0	0	2	0	4	24
Nonresident Pharmacy	10	3	1	1	7	5	3	2	10	3	10	2	57
Licensed Correctional Facility	1	0	0	0	0	0	1	0	1	0	0	0	3
Hypodermic Needle and Syringes	1	5	1	3	2	1	1	1	2	0	1	0	18
Nonresident Wholesalers	10	13	16	4	9	2	11	3	6	3	8	5	90
Wholesalers	8	7	15	4	3	2	3	0	5	0	5	6	58
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	1	0	0	0	0	0	1
Designated Representatives	45	26	40	44	11	26	31	8	56	41	57	39	424

*u/a denotes unavailable

** denotes corrected

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

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Pending													
Pharmacist Examination	241	283	192	217	196	141	172	139	845	563	808	756	756
Intern pharmacist	278	496	488	320	159	226	201	235	270	248	270	291	291
Pharmacy technician	1894	1888	1837	1969	1451	2704	2121	2050	3262	3209	3119	2490	2490
Pharmacy	58	54	49	42	47	65	52	53	57	70	72	76	76
Sterile Compounding	18	18	13	12	16	19	19	17	25	32	27	22	22
Clinics	30	28	24	37	36	32	27	30	29	32	46	34	34
Hospitals	19	16	12	14	14	9	9	9	11	9	9	7	7
Nonresident Pharmacy	34	32	33	39	36	38	36	37	42	50	40	43	43
Licensed Correctional Facility	0	0	0	0	0	0	1	1	0	0	0	0	0
Hypodermic Needle and Syringes	19	10	11	12	10	10	6	4	5	15	13	13	13
Nonresident Wholesalers	92	79	72	79	73	79	70	66	70	90	77	75	75
Wholesalers	43	35	20	23	31	36	34	36	43	48	43	44	44
Veterinary Food-Animal Drug Retailer	1	1	1	2	2	2	0	0	0	0	0	0	0
Designated Representatives	132	88	128	119	159	167	163	168	197	211	166	167	167
Change of Pharmacist-in-Charge***													
Received	189	159	130	182	119	134	160	43	36	128	138	133	1551
Processed	151	91	75	132	40	109	42	112	133	46	112	105	1148
Pending	38	106	161	211	290	315	433	364	267	349	375	403	403
Change of Exemptee-in-Charge***													
Received	37	22	19	14	12	14	9	6	5	9	14	11	172
Processed	6	7	0	13	1	9	12	0	10	0	0	10	68
Pending	31	46	65	66	77	82	79	85	80	89	103	104	104
Change of Permits													
Received	347	103	74	100	39	50	46	49	43	37	69	87	1044
Processed	37	1	311	57	90	67	126	9	46	0	2	120	866
Pending	310	412	175	218	167	150	70	110	107	144	211	178	178
Discontinuance of Business***													
Received	42	33	35	42	37	35	12	21	0	15	13	12	297
Processed	35	12	18	21	19	14	8	1	14	17	2	21	182
Pending	7	28	45	66	84	105	109	129	115	113	124	115	115

*u/a denotes unavailable

** denotes corrected

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

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

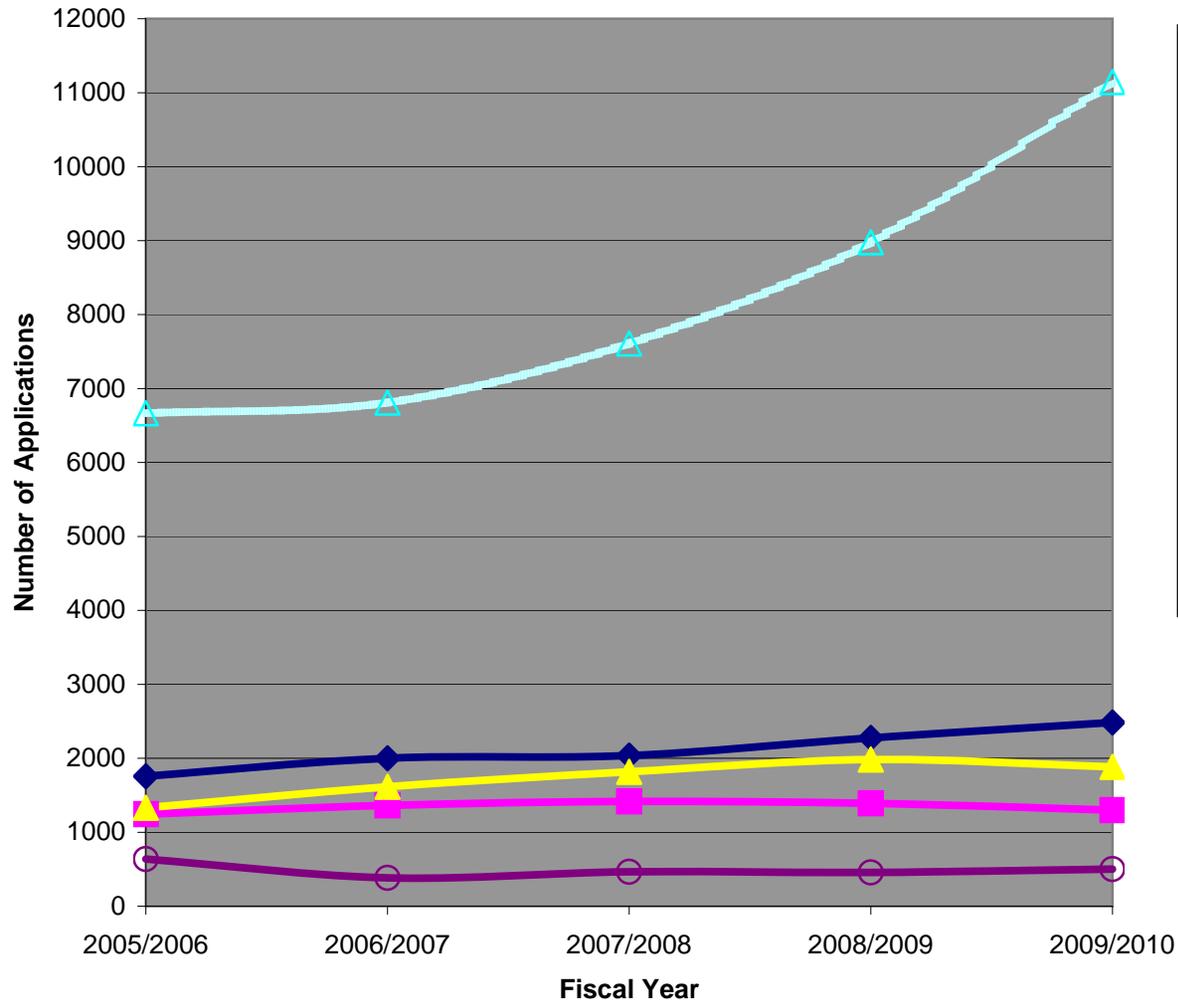
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1213	2757	2836	1640	839	1687	1640	1340	1446	1143	844		17385
Pharmacy technician	1632	3740	4021	1716	527	2181	2059	2053	2224	1810	401		22364
Pharmacy	182	484	641	991	377	460	395	442	863	1134	448		6417
Sterile Compounding	21	49	74	17	24	23	21	3	14	24	4		274
Clinics	76	131	187	70	55	80	100	87	61	86	34		967
Nonresident Pharmacy	34	31	53	14	23	17	21	21	36	27	8		285
Licensed Correctional Facility	0	1	27	0	6	0	0	0	0	0	0		34
Hypodermic Needle and Syringes	10	23	41	37	16	26	22	11	23	14	9		232
Nonresident Wholesalers	32	54	64	40	27	33	38	37	49	43	21		438
Wholesalers	32	71	71	30	20	41	37	20	35	39	17		413
Veterinary Food-Animal Drug Retailer	2	4	2	1	5	4	4	5	1	1	3		32
Designated Representative	149	306	320	192	145	139	135	116	246	219	52		2019

*u/a denotes unavailable

** denotes corrected

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

Number of Applications Received - Personal Licenses



Percentage Change

Pharmacist (exam applications): 41%

Pharmacist (initial licensing applications): 4%

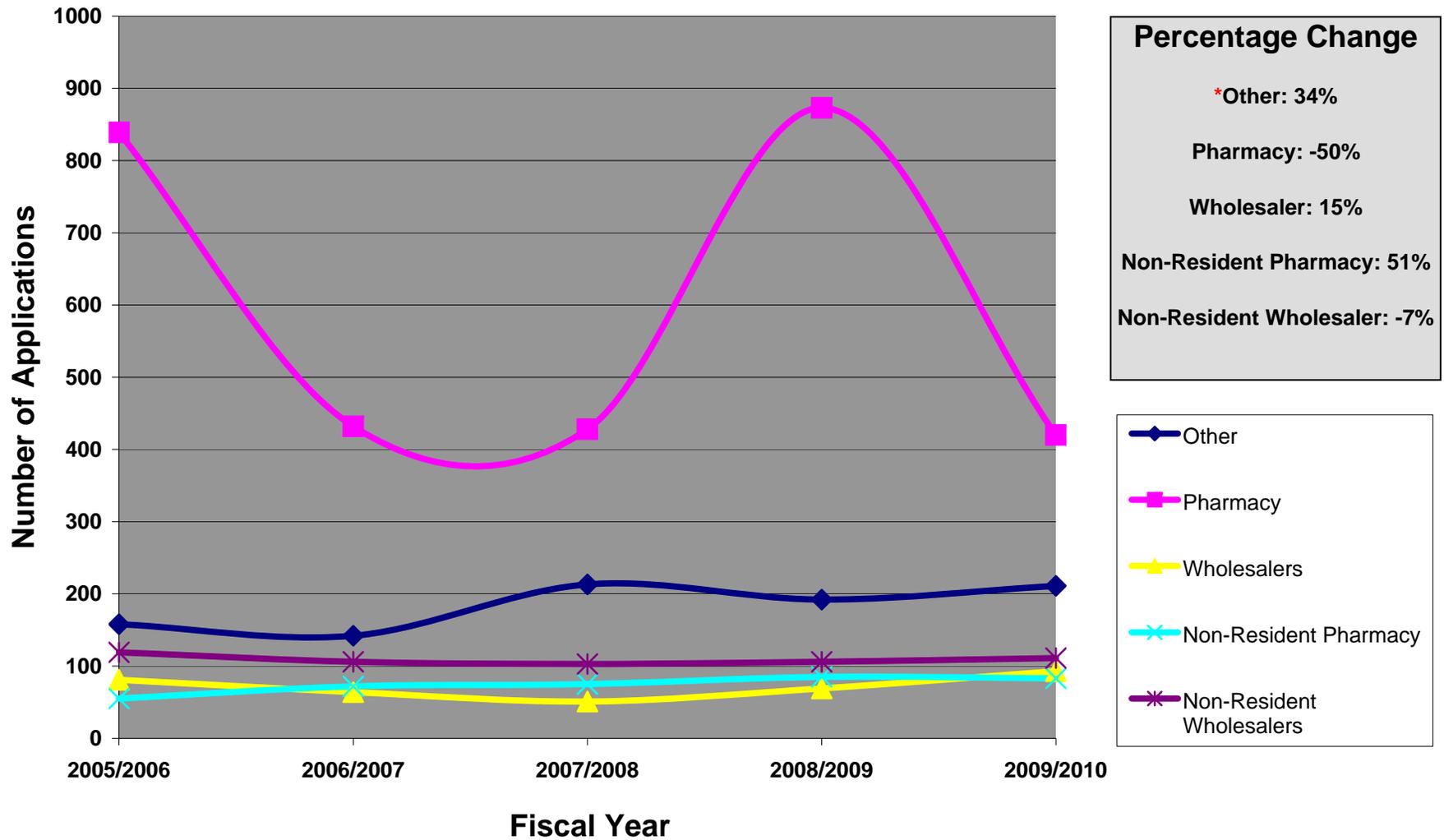
Intern Pharmacist: 42%

Technicians: 67%

Designated Representatives: - 21%

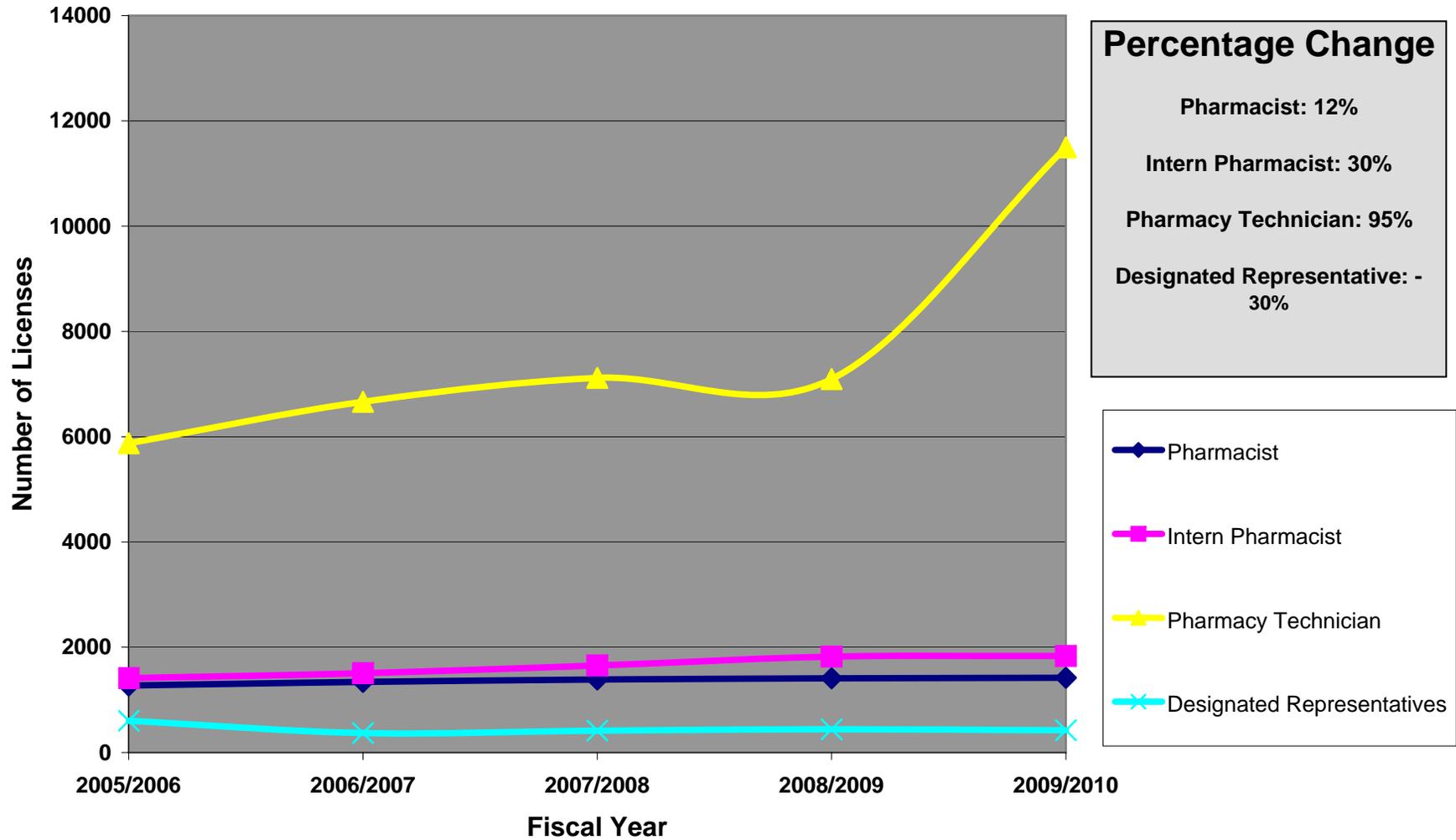


Number of Applications Received - Site Licenses

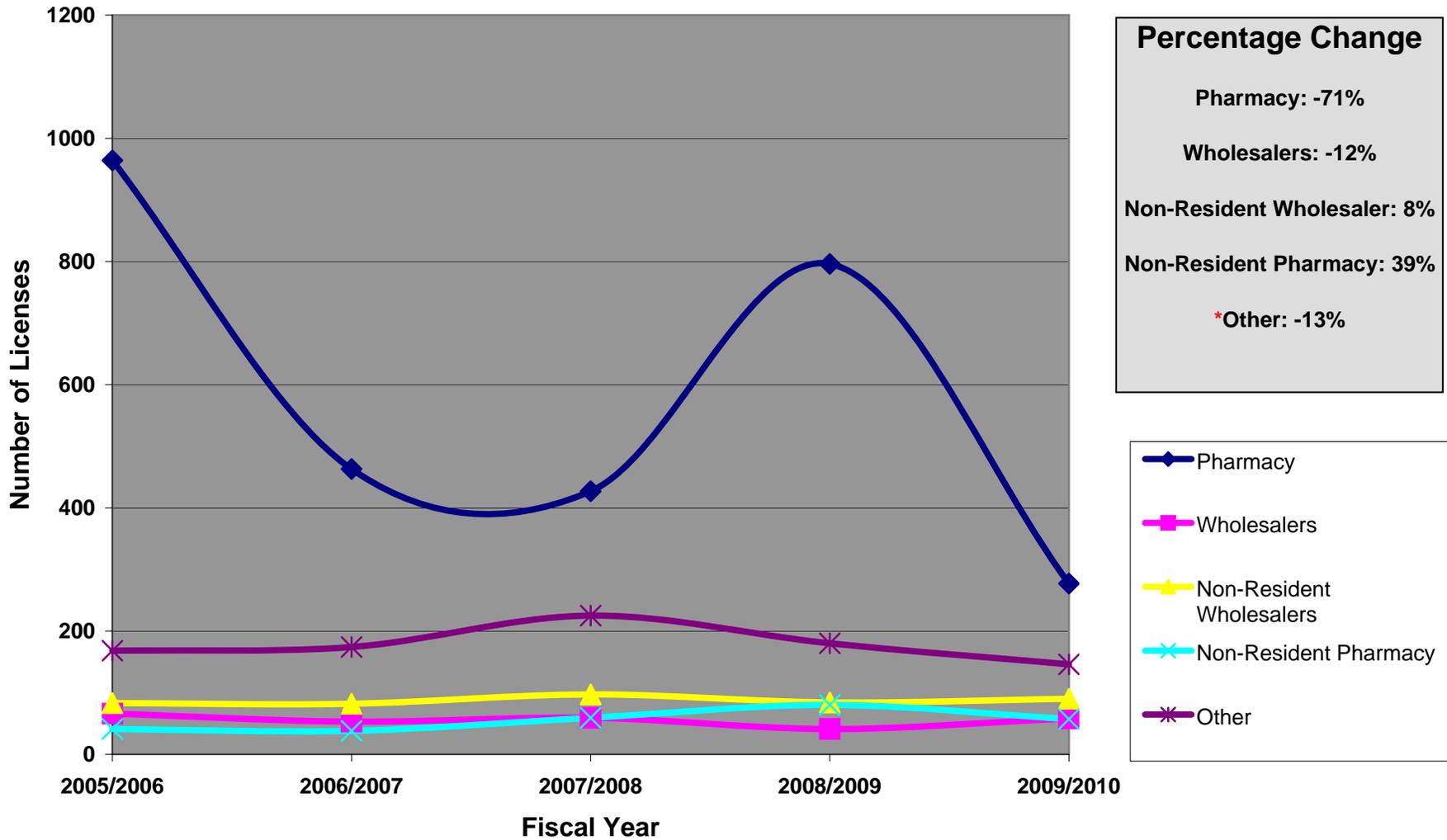


*Other= Sterile Compounding, Clinics, Hospitals, Licensed Correctional Facility, Hypodermic Needle and Syringes, Veterinary Food-Animal Drug

Number of Licenses Issued - Personal

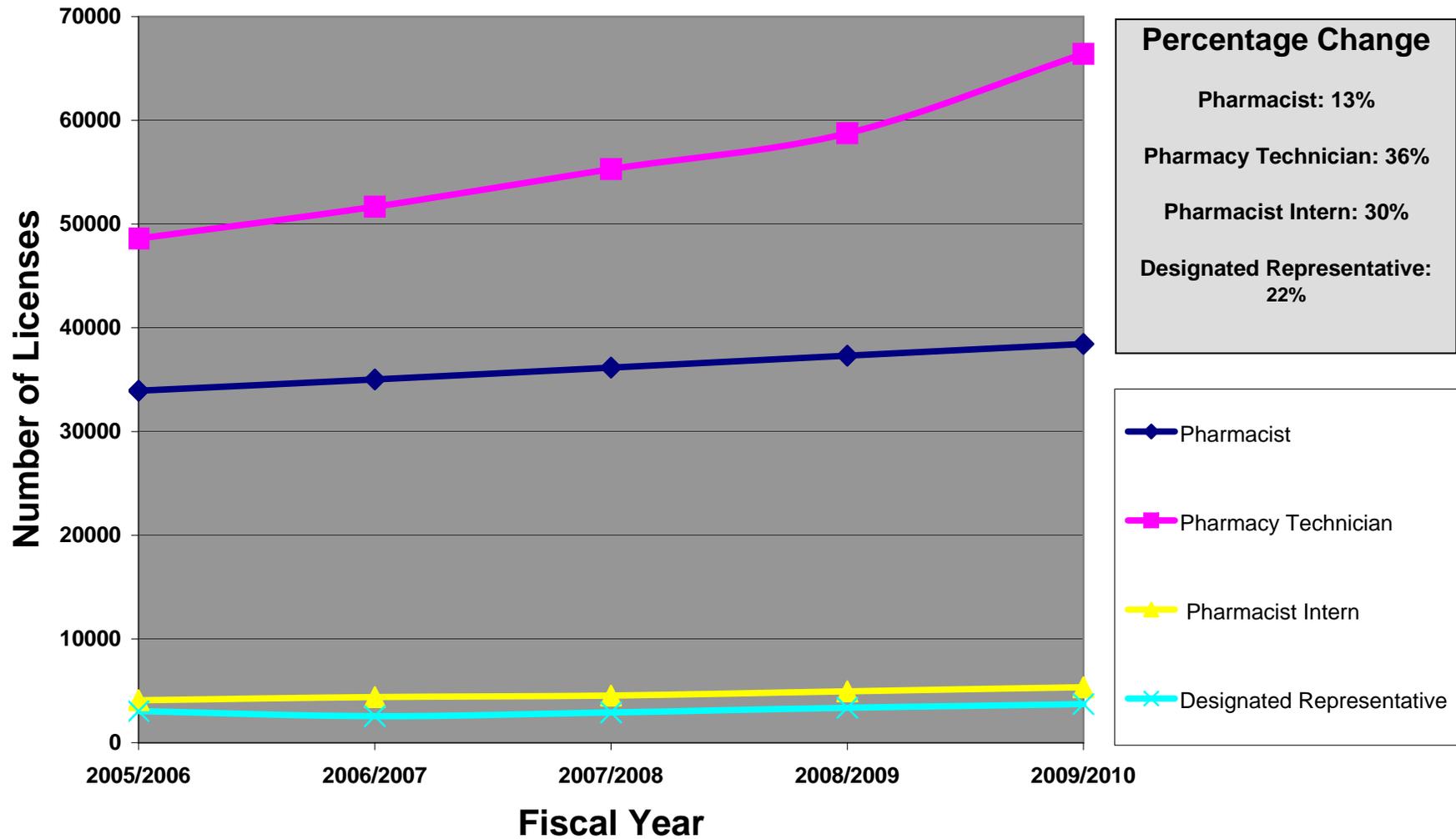


Number of Licenses Issued - Site

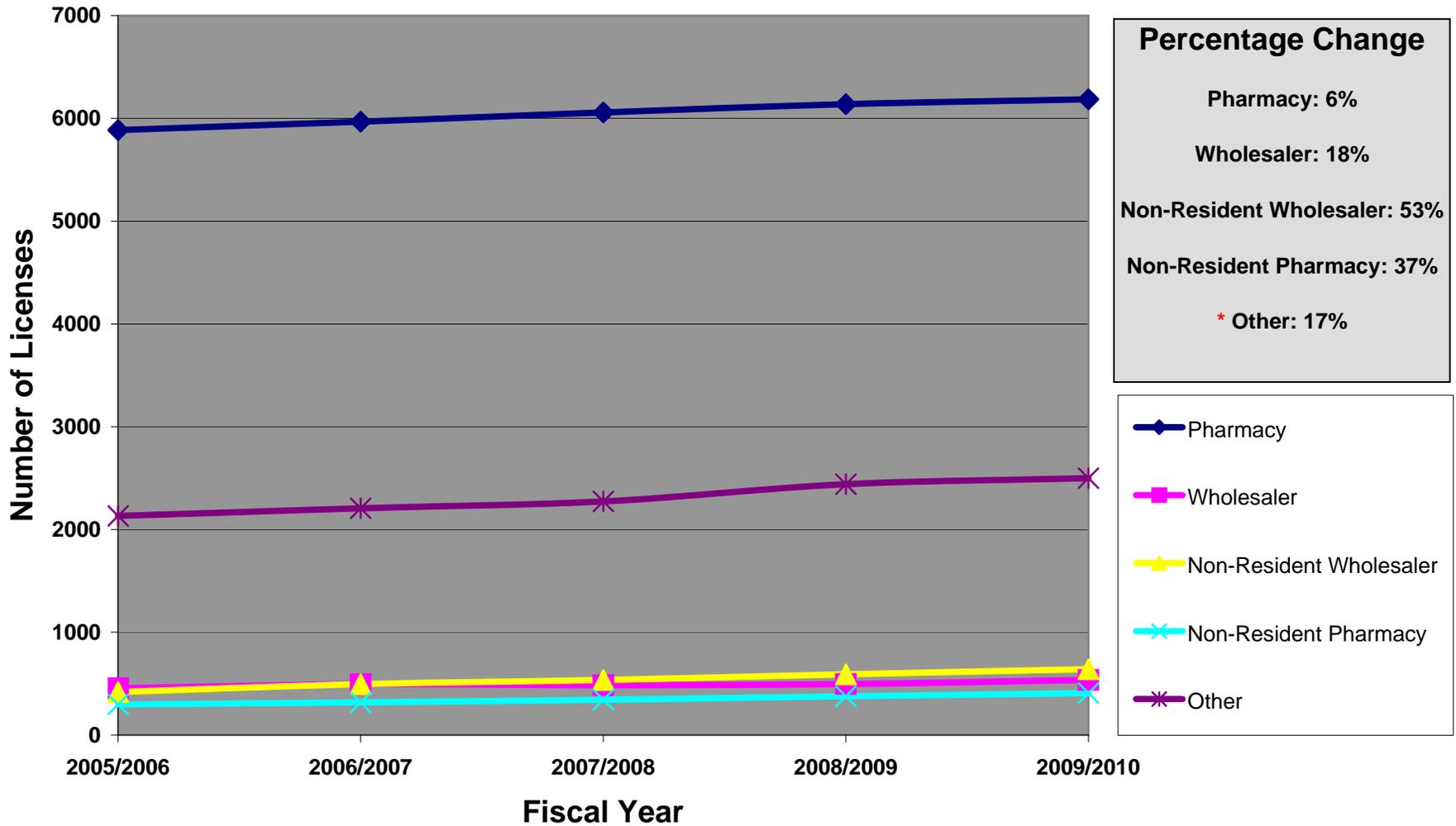


*Other= Sterile Compounding, Clinics, Hospitals, Licensed Correctional Facility, Hypodermic Needle and Syringes, Veterinary Food-Animal Drug

Number of Licenses - Personal



Number of Licenses - Site



*Other= Sterile Compounding, Clinics, Hospitals, Licensed Correctional Facility, Hypodermic Needle and Syringes, Veterinary Food-Animal Drug

ATTACHMENT 11

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)	451	349	307	1234	40	25	29	19
	Pharmacist (initial licensing)	728	244	250	113	2	2	4	4
	Pharmacy Intern	871	456	270	298	19	20	61	18
	Pharmacy Technician	2,885	2,716	2,726	3239	69	72	58	36
	Pharmacies	80	68	72	260	25	18	23	19
	Non-Resident Pharmacy	12	12	31	28	38	33	35	27
	Wholesaler	18	26	14	35	30	31	31	19
	Veterinary Drug Retailers	0	0	0	0	0	0	0	0
	Designated Representative	127	142	114	118	30	32	29	22
	Out-of-state distributors	27	24	13	47	30	34	33	29
	Clinics	25	21	15	34	45	20	28	29
	Hypodermic Needle & Syringe Distributors	6	4	2	0	30	1	21	0
	Sterile Compounding	9	8	17	20	30	8	10	29
	Change of Permit	405	189	138	193	32	45	45	45
	Pharmacist in Charge	478	435	239	399	14	14	30	30
	Designated Representative in Charge	78	40	20	34	14	14	30	30
	Discontinuance of Business	110	114	31	40	30	30	30	30

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)	15	15	15	5
Pharmacist (initial licensing)	7	7	7	7
Pharmacy Intern	15	15	15	7
Pharmacy Technician	15	15	15	14
Pharmacies	15	15	15	12
Non-Resident Pharmacy	7	7	5	5
Wholesaler	7	7	5	5
Veterinary Drug Retailers	0	0	0	0
Designated Representative	7	7	5	5
Out-of-state distributors	7	7	5	5
Clinics	20	15	15	12
Hypodermic Needle & Syringe	7	7	5	5

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	2	2
Pharmacist (initial licensing)	2	2	2	2
Pharmacy Intern	2	2	2	2
Pharmacy Technician	5	5	5	3
Pharmacies	2	2	5	5
Non-Resident Pharmacy	3	3	10	7
Wholesaler	2	3	10	7
Veterinary Drug Retailers	0	0	0	0
Designated Representative	1	2	5	2
Out-of-state distributors	2	3	10	7
Clinics	1	2	7	3
Hypodermic Needle & Syringe	1	2	5	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	690	384	233	114
Pharmacy Intern	639	696	136	362
Pharmacy Technician	2,303	2,544	2,614	4,038
Pharmacies	108	45	77	74
Non-Resident Pharmacy	14	13	15	15
Wholesaler	30	9	8	11
Veterinary Drug Retailers	0	0	1	0
Designated Representative	111	81	95	137
Out-of-state distributors	39	15	20	16
Clinics	20	15	17	10
Hypodermic Needle & Syringe	7	6	4	1
Sterile Compounding	18	1	3	16

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	95	20	141	72
Pharmacies	0	0	21	3
Non-Resident Pharmacy	1	1	3	4
Clinics	0	0	1	4
Sterile Compounding	0	1	1	1
Designated Representative	19	0	21	31
Hypodermic Needle & Syringe	4	0	5	2
Out-of-state distributors	11	4	5	15
Wholesaler	9	0	8	9
Veterinary Drug Retailers	0	0	1	0
Registered Pharmacist	0	0	62	178
Intern Pharmacist	0	0	57	0

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

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	0	1	0	7
Intern Pharmacist	0	0	0	2
Pharmacy Technician	32	6	7	35
Pharmacies	0	1	0	1
Non-Resident Pharmacy	0	0	0	1
Clinics	0	0	0	0
Sterile Compounding	0	0	0	0
Designated Representative	1	0	0	1
Hypodermic Needle & Syringe	0	0	0	0
Out-of-state distributors	0	0	0	0
Wholesaler	0	0	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	863	852	962	1,373
Pharmacy Technicians	1,214	1,333	2,411	1,611
Site licenses (pharmacy, clinics)	716	1,216	989	565
Site licenses (wholesalers, nonresident pharmacies)	701	695	608	583
Pharmacist in Charge	358	761	***	30****
Renewals	533	715	***	275

8. Responding to telephone status request and inquiries.

	Qtr 1 *	Qtr 2 **	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	100	153	84	134
Pharmacy Technicians	100	64	0	0
Site licenses (pharmacy, clinics)	200	237	368	287
Site licenses (wholesalers, nonresident pharmacies)	151	278	220	194
Pharmacist in Charge	143	98	***	***
Renewals	112	51	***	186

* 1st Qtr - E-mail and voicemail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 8/21/09-9/11/09 to allow board staff time to focus on processing applications and issuing licenses.

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

*** Qtr - Not available.

**** Suspended 4th Qtr 6/21/10 - 7/15/10

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:	<table border="1" data-bbox="370 289 1515 798"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Revenue Received:</th> <th colspan="4">Average Days to Process:</th> </tr> <tr> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3*</th> <th>Qtr 4**</th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Applications</td> <td>\$513,971</td> <td>\$466,525</td> <td>\$259,396</td> <td>\$277,016</td> <td>2</td> <td>3</td> <td>3.5</td> <td>3</td> </tr> <tr> <td>Renewals</td> <td>\$2,325,121</td> <td>\$1,748,422</td> <td>\$1,295,728</td> <td>\$1,295,728</td> <td>2</td> <td>3</td> <td>4.5</td> <td>3</td> </tr> <tr> <td>Cite and Fine</td> <td>\$285,685</td> <td>\$210,295</td> <td>\$325,035</td> <td>\$273,620</td> <td>4</td> <td>7</td> <td>7</td> <td>7</td> </tr> <tr> <td>Probation/ Cost Recovery</td> <td>\$38,031</td> <td>\$64,631</td> <td>\$179,510</td> <td>\$31,328</td> <td>4</td> <td>6</td> <td>9</td> <td>6</td> </tr> <tr> <td>Request for Information/ License Verification</td> <td>\$4,760</td> <td>\$5,770</td> <td>\$650</td> <td>\$4,785</td> <td>3</td> <td>2</td> <td>2</td> <td>2</td> </tr> <tr> <td>Fingerprint Fee</td> <td>\$16,346</td> <td>\$17,465</td> <td>\$9,481</td> <td>\$17,646</td> <td>2</td> <td>2</td> <td>3.5</td> <td>2</td> </tr> </tbody> </table> <p data-bbox="370 840 1515 945">* 3rd quarter data reported at the last board meeting reflected January and February 2010 only as these were the only data available at that time. 2nd quarter data is now complete and the revised data are displayed above.</p> <p data-bbox="370 945 1515 1008">** 4th quarter reflects April and May 2010 data available at the time of report development.</p>										Revenue Received:				Average Days to Process:				Qtr 1	Qtr 2	Qtr 3*	Qtr 4**	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Applications	\$513,971	\$466,525	\$259,396	\$277,016	2	3	3.5	3	Renewals	\$2,325,121	\$1,748,422	\$1,295,728	\$1,295,728	2	3	4.5	3	Cite and Fine	\$285,685	\$210,295	\$325,035	\$273,620	4	7	7	7	Probation/ Cost Recovery	\$38,031	\$64,631	\$179,510	\$31,328	4	6	9	6	Request for Information/ License Verification	\$4,760	\$5,770	\$650	\$4,785	3	2	2	2	Fingerprint Fee	\$16,346	\$17,465	\$9,481	\$17,646	2	2	3.5	2
	Revenue Received:				Average Days to Process:																																																																											
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Fingerprint Fee	\$16,346	\$17,465	\$9,481	\$17,646	2	2	3.5	2																																																																								

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.																																												
Measure:	Percentage of licensing records changes within five working days.																																												
Tasks:	<table border="1" data-bbox="370 289 1523 571"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Requests Received:</th> <th colspan="4">Average Days to Process:</th> </tr> <tr> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Address/Name Changes</td> <td>1,830</td> <td>2,178</td> <td>2070</td> <td>2840</td> <td>15</td> <td>10</td> <td>13</td> <td>9</td> </tr> <tr> <td>Off-site Storage Applications (approved)</td> <td>0</td> <td>0</td> <td>61</td> <td>38</td> <td>0</td> <td>0</td> <td>16</td> <td>5</td> </tr> <tr> <td>Transfer of Intern Hours to Other States</td> <td>200</td> <td>17</td> <td>214*</td> <td>237**</td> <td>15</td> <td>15</td> <td>15</td> <td>20</td> </tr> </tbody> </table> <p data-bbox="370 615 987 682">* Updated to include March 2010 data. ** June 2010 data not available at time of report.</p>		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	1,830	2,178	2070	2840	15	10	13	9	Off-site Storage Applications (approved)	0	0	61	38	0	0	16	5	Transfer of Intern Hours to Other States	200	17	214*	237**	15	15	15	20
	Requests Received:				Average Days to Process:																																								
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4																																					
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Off-site Storage Applications (approved)	0	0	61	38	0	0	16	5																																					
Transfer of Intern Hours to Other States	200	17	214*	237**	15	15	15	20																																					

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1490 285">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores. <li data-bbox="370 516 1490 657">2. Evaluate the drug distribution system of clinics and their appropriate licensure. <i>1st Qtr 09/10:</i> Continued to advise clinics and their advocates about the barrier the Capen decision places on surgicenters/clinics from obtaining a board clinic permit. A legislative solution is needed. <i>3rd Qtr 09/10:</i> Board hears presentation by Fort Sutter Surgery Center discussing the issue. <li data-bbox="370 699 1490 951">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure. <li data-bbox="370 961 1490 1287">4. Work with local and state officials on emergency preparedness and planning for pandemics and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>2nd Qtr 09/10:</i> Board votes that in declared emergencies where a board meeting cannot quickly be scheduled, a subcommittee of three members can make decisions for patient safety under provisions of Business and Professions Code section 4062 and the board's emergency response policy. <i>4th Qtr 09/10:</i> Licensing continued reviewing requests from CDPH seeking clarification on board disaster response policy. <li data-bbox="370 1297 1433 1325">5. Evaluate the need to issue a provisional license to pharmacy technician trainees.

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

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

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

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

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

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

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

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

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

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

7. Review requirements for qualifications of pharmacy technicians with stakeholders

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

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

Board participates in CSHP sponsored stake holder meeting.

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

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

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

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

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| | <p>20. Automate fingerprint background results with the Department of Justice.
<i>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).</i>
<i>3rd Qtr 09/10: Continued working with the DCA on developing programming specifics in order to go live on February 17, 2010.</i>
<i>Board staff develops the procedures.</i>
<i>4th Qtr 09/10: Final revision to the procedures, trained staff, and assigned job task to staff.</i>
<i>Board staff continues to manage automated process and resolve issues.</i></p> <p>21. Evaluate pharmacy technician application process to identify areas for improvement.
<i>3rd Qtr 09/10: Staff reached out to pharmacy technician programs to advise them of statutory changes to the application fee.</i>
<i>Staff revised pharmacy technician application after reviewing most common deficiencies for legal review.</i>
<i>4th Qtr 09/10: Staff reached out to pharmacy technician programs educating them on the most common application deficiencies.</i></p> <p>22. Implement Fingerprint Requirement for Pharmacist Renewal.
<i>4th Qtr 09/10: Regulation approved by Office of Administrative Law (effective date of regulation is December 7, 2010).</i>
<i>Department drafted programming changes to accommodate requirement.</i>
<i>Board staff tested changes in a testing environment.</i></p> <p>23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership.
<i>4th Qtr 09/10: Board staff developed standards for common ownership requirements.</i></p> |
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