# *AGENDA ITEM B*

**State of California** **Department of Consumer Affairs**

# Memorandum

**To:** **Licensing Committee**
**Board of Pharmacy**

**Date: June 10, 2003**

**From:** **Anne Sodergren**
**Staff Services Manager**

**Subject:** **Foreign Pharmacy Graduate Equivalency Examination Update**

As a result of the security breach administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) was suspended until a new test was developed and the investigation was completed. The new FGPEE test has been developed and is scheduled to be administered for the first time June 21, 2003, to approximately 2100 candidates, The new test is not computer based but will be given in 4 cities nationwide, including one location in California. NABP anticipates results will be released by the end of August.

There is no set date for any subsequent administrations, but NAPB anticipates the next administration to be in late 2003 or early 2004.

As reported at the last licensing committee meeting, NABP identified 15 individuals implicated to Internet postings which may have caused or contributed to the compromise. As such the scores of those candidates were invalidated. None of the individuals listed are licensees or have pending applications with the board.

*AGENDA ITEM D*

**California State Board of Pharmacy**
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

**NO ACTION**
**REPORT ONLY**

# COMPETENCY COMMITEE REPORT TO THE BOARD MEMBERS FROM THE LICENSING COMMITTEE CLARENCE HIURA, CHAIR JUNE 10, 2003

## 1. Report on the June 2003 Examination

On June 17 and 18, 2003, the board will administer its June 2003 pharmacist licensure examination at the San Jose Convention and Cultural Facilities. As of June 10, 2003, 1324 candidates have been scheduled for the examination.

Grading for this exam will be conducted in Sacramento on July 16 and 17, 2003. Board member graders are needed for this administration. Please contact Debbie Anderson to make the necessary arrangements if you are willing to participate in the grading session.

Examination results are scheduled to be released approximately September 1, 2003. Passing rate information will be available at the October 2003 board meeting.

## 2. Report on the January 2004 Examination

On January 13 and 14, 2004, the board will administer its January 2004 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel.

Staff Contact: Debbie Anderson
(916) 445-5014, ext. 4007

# *AGENDA ITEM E*

State of California Department of Consumer Affairs

# Memorandum

To: Licensing Committee Date: June 10, 2003

From: Virginia Herold
Assistant Executive Officer

Subject: Implementation of Sterile Compounding Program

## *Update on the Board's Newest Licensing Program*

On July 1, 2003, any California pharmacy that compounds sterile injectable drug products must be licensed by the board as a compounding pharmacy unless the pharmacy is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Commission on Healthcare (ACHC).

Additionally any nonresident pharmacy that ships injectable sterile compounded products into California that is not licensed as a hospital, home health agency or a skilled nursing facility and has current accreditation from JCAHO or ACHC must obtain a nonresident sterile compounding license from the board.

When licensure is required, part of the application process requires that the board must inspect the pharmacy. For nonresident pharmacies, the board is required to obtain a copy of an inspection report from the state pharmacy licensing agency or accreditation agency.

For the prior four months, board staff has been implementing this program. Application forms have been developed, programming for licensing records performed, training of staff provided in processing applications and conducting inspections, and information sessions with the profession conducted. As with anything done at the board, this has been a team effort, but Supervising Inspector Dennis Ming has been instrumental in establishing the program. Suelynn Yee is processing the applications.

Applications are on the board's Web site for downloading by pharmacies. A self-assessment form has been developed so that pharmacies can review what elements inspectors will check during inspections. There have been a number of questions asked of diverse board staff regarding compliance and the process.

Until June 1, few applications had been submitted. As of today the board has received 54 applications. Fourteen of these have been approved for licensure. Only two applications are from out-of-state.

However, the board knows that at least another 51 applications will be coming from California sites that perform sterile compounding of injectables, and there could be numerous additional locations that perform these services that may submit applications.

To assure that the board will have inspected all sites possible before July 1, all board inspectors have been assigned inspections of pharmacies seeking this specialty license as a priority assignment. The board's staff will make every effort to process the application elements and conduct the inspections as quickly (yet thoroughly) as possible.

The greatest obstacle to licensure has been the policy and procedures (review of which is a required element of the application process). In many cases the written policy and procedures do not conform to a pharmacy's actual procedures or are incomplete.

The board has also sent a letter to all state boards of pharmacy, advising them of California's requirements for compounding sterile injectables that are shipped into the state by pharmacies, and the requirement that an inspection report be submitted as part of the nonresident pharmacy application. We believe that the self-assessment form will help other states' inspectors in performing this review.

As determined by the board at its October 2002 Board Meeting, the board's existing regulations for compounding parenterals is the standard the board is enforcing with respect to licensure. Meanwhile the board is promulgating additional regulations to deal with requirements for compounding injectables from nonsterile ingredients. At the April 2003 meeting, changes to this regulation were adopted and released for 15 days of comment. The responses are due back by June 19. These new requirements will take effect in January 2005, if the regulation is approved.

*AGENDA ITEM F*

**State of California** **Department of Consumer Affairs**

# Memorandum

**To:** **Licensing Committee** **Date: June 11, 2003**

**From:** **Patricia F. Harris**
**Executive Officer**
**Board of Pharmacy**

**Subject:** **Review of Intern Program and Requirements**

One of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. Because of other priorities, this committee has not had the opportunity to perform such a review.

Therefore, the purpose of this agenda item is to begin this by soliciting comments on how the intern program should be updated and streamlined operationally. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website.

For background material, I have attached the regulations governing interns and the intern experience affidavits that interns submit to meet the requirements of CCR 1728(c).

choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

**§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.**

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy school approved by the American Council on Pharmaceutical Education or recognized by the board.
(b) A final examination must be a part of the course of study.
(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

**§1726. Preceptor.**

(a) A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.
(b) The preceptor shall supervise the intern's activities to provide the experience necessary to make the intern proficient in the provision of pharmaceutical services.
(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

**§1727. Intern Pharmacist.**

(a) An intern pharmacist is a person who holds a valid intern card.
(b) An intern card shall be issued for a period of:
(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.
(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.
(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.
(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.
(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:
(1) Persons who have not completed experience requirements.
(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.
(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.
(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

**§1728. Intern Experience--Requirements for Licensure.**

(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.

(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.

(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.

(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.

(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:

(1) Receiving and interpreting the prescription;
(2) Patient medication profiles;
(3) Prescription preparation;
(4) Consultation;
(5) Record keeping;
(6) Over the counter products;
(7) Drug information.

(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.

(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.

Authority cited: Sections 4005 and 4114, Business and Professions Code. Reference: Sections 4114 and 4200, Business and Professions Code.

## Article 4. Continuing Education

**§1732. Definitions.**

As used in this article:

(a) An accreditation agency is an organization which evaluates providers of continuing pharmaceutical education, monitors the quality of their educational activities, and audits continuing education coursework.

(b) The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.

(c) The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.

(d) A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.

(e) An hour consists of at least 50 minutes of contact time.

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

**§1732.05. Accreditation Agencies.**

(a) The following organizations are approved by the Board as continuing education and accreditation agencies:

*COMMUNITY PHARMACY INTERNSHIP OBJECTIVES*

# PHARMACY INTERN EXPERIENCE AFFIDAVIT

Name of Applicant: _____ Social Security Number * _____
(please print) Last name First name MI

Intern No.: _____ Date Issued: _____ Expiration Date: _____

**INSTRUCTIONS:** It is the intern's responsibility to seek preceptors and internship sites that will provide him or her at a minimum with those experiences outlined below. As each objective is mastered, the preceptor should date and initial the line opposite the objective. All preceptors who date and initial the form must also sign at the end of this form.

| ***Receiving and Interpreting the Prescription*** | **Date Mm/dd/yy** | **Preceptor's Initials** |
|---|---|---|
| 1. The intern is able to receive a prescription and obtain and clarify all necessary information (e.g., name, date, correct spelling, address, age and weight if appropriate, name of prescriber, and third-party information). | ___/___/___ | _____ |
| 2. The intern, upon receiving a telephone prescription from a prescriber or his or her agent, is able to record the information accurately and completely, noting the identity of the caller. | ___/___/___ | _____ |
| 3. The intern is able to detect errors and omissions in a prescription or medication order, and can take appropriate action to correct them. | ___/___/___ | _____ |
| 4. The intern is able to establish and maintain manual or computerized prescription profiles (e.g., patient history, drug information, third-party information). | ___/___/___ | _____ |
| 5. The intern is able to use the patient medication profile to monitor drug utilization, note drug interactions, allergies and sensitivities, and is able to take appropriate action to correct drug-related problems. | ___/___/___ | _____ |
| 6. The intern is able to determine when it is legal and/or appropriate to refill a prescription. When necessary, the intern is able to obtain the prescriber's authorization and document the transaction. | ___/___/___ | _____ |
| 7. The intern is able to recognize a situation in which an individual may be passing either a forged prescription or a prescription which is valid on its face but in all probability is not for legitimate medical use. The intern is able to determine if either of these is the case, and knows the process to notify the appropriate authorities. | ___/___/___ | _____ |
| ***Prescription Preparation, Dispensing and Control*** | | |
| 1. The intern is able to select the correct drug product, including drug entity, manufacturer, dose, and dosage form and is able to accurately prepare the prescription for dispensing. | ___/___/___ | _____ |
| 2. The intern can prepare or supervise the preparation of the prescription label (generated manually or by computer) for a given prescription which conforms to all state and federal regulations. The intern is able to assure that the label conveys directions in a manner understandable to the patient and that appropriate auxiliary labels are attached. | ___/___/___ | _____ |

3. The intern is able to select an appropriate container for storage or use of medications with special requirements (e.g., child-resistant containers, compliance devices). ___/___/___ _____

4. The intern is able to perform the necessary calculations and demonstrate the required pharmaceutical skills (weighing, trituration, dilution, etc.), to produce a pharmaceutically-elegant product. The intern is able to accurately document all necessary steps and procedures involved in compounding of that product. ___/___/___ _____

5. The intern is able to perform a final check of the prescription with regard to correct drug, dose, dosage form, and accuracy and clarity of labeling. ___/___/___ _____

6. The intern is able to appropriately dispose of outdated, discontinued or recalled drugs, controlled substances, needles and syringes, and cytotoxic agents. ___/___/___ _____

***Consultation with Patients and Health Providers***

1. The intern is able to effectively communicate all information necessary to encourage proper use and storage of the medication. This includes the importance of compliance with directions, and precautions and relevant warnings. The intern routinely verifies that the patient understands this information. ___/___/___ _____

2. The intern is able to effectively communicate with other health professionals for such purposes as counseling, discussing the therapeutic plan, and providing education. ___/___/___ _____

3. The intern is able to assess a patient's self-identified problem to determine if the problem requires the pharmacist's intervention or a medical referral. ___/___/___ _____

4. The intern is able to transfer a prescription and relevant information to another pharmacist and document the transaction properly. ___/___/___ _____

***Record Keeping***

1. The intern is able to establish and maintain manual or computerized files of current prescription records in conformance with state and federal laws and regulations. ___/___/___ _____

2. The intern is able to maintain suitable records for poisons, DEA-controlled substances and syringes and needles that are received, stored and furnished by the pharmacy. ___/___/___ _____

***Non-Prescription Products***

1. The intern is able to assess a patient's complaints and discuss the options for therapy. Where the use of a non-prescription medication is indicated, the intern is able to make recommendations and counsel the patient about the proper use of the product(s). ___/___/___ _____

2. The intern is able to instruct a patient on the proper use of a diagnostic agent or device including directions for obtaining accurate results and interpreting the results. ___/___/___ _____

3. The intern is able to instruct a patient on the proper and safe use of commonly used health products such as condoms, thermometers, metered-dose devices, ear syringes, and compliance devices. ___/___/___ _____

4. The intern is able to instruct a patient on the proper and safe use of durable medical equipment and home health supplies. ___/___/___ _____

***Drug Information***

1. The intern is able to identify an unidentified drug dosage form using appropriate resources or refer the question to an appropriate source. ___/___/___ _____

2. The intern is able to evaluate the urgency of a poisoning or overdose situation, supply general information on the initial treatment, and refer the problem to the nearest poison information center, if necessary. ___/___/___ _____

3. The intern is able to effectively select and use appropriate references to answer drug information requests and/or refer the questions to another source for response. ___/___/___ _____

*I certify, under penalty of perjury, that all objectives I have initialed have been met. To the best of my knowledge, the experience thus gained by this applicant has been predominantly related to the practice of pharmacy, as required by law.*

| Preceptor's Name | Initials | RPh # | State | Date |
|---|---|---|---|---|
| Preceptor's Name | Initials | RPh # | State | Date |
| Preceptor's Name | Initials | RPh # | State | Date |
| Preceptor's Name | Initials | RPh # | State | Date |

*Disclosure of your social security number is mandatory. Business and Professions Code section 30 and Public Law 94-455 (42 USCA 405(c)(2)(C) authorize collection of your social security number. Your social security number will be used exclusively for tax enforcement purposes of compliance with any judgement or order for family support in accordance with section 11350.6 of the Welfare and Institutions Code, or for verification of examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security number, your application for initial or renewal license will not be processed AND you will be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

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17A-30A (rev 3/99)

*INSTITUTIONAL PHARMACY INTERNSHIP OBJECTIVES*

# PHARMACY INTERN EXPERIENCE AFFIDAVIT

Name of Applicant: _____ Social Security Number * _____
(please print) Last name First name MI

Intern No.: _____ Date Issued: _____ Expiration Date: _____

**INSTRUCTIONS:** It is the intern's responsibility to seek preceptors and internship sites that will provide him or her at a minimum with those experiences outlined below. As each objective is mastered, the preceptor should date and initial the line opposite the objective. All preceptors who date and initial the form must also sign at the end of this form.

| ***Receiving and Interpreting the Prescription*** | **Date Mm/dd/yy** | **Preceptor's Initials** |
|---|---|---|
| 1. The intern is able to determine which portions of the chart orders contain the medication orders and information related to monitoring and adjustment of drug therapy. | ___/___/___ | _____ |
| 2. The intern is familiar with the policies and procedures for drug distribution and administration (receipt of the medication order, computer entry and verification, filling and delivery of the medication(s) by the pharmacy, receiving, storage, and recording keeping at the nursing unit, and administration of the drug to the patient). | ___/___/___ | _____ |
| 3. The intern is able to assess the medication order for appropriateness in terms of dosage, route of the prescribed drug therapy, frequency and rate of administration, directions for use, delivery method, drug interactions and incompatibilities, and stability and proper storage. | ___/___/___ | _____ |
| 4. The intern is able to identify an incorrect, incomplete or unclear order and obtain all information or clarify the document to make it complete and appropriate for dispensing. | ___/___/___ | _____ |
| 5. The intern is able to use appropriate judgment to determine the immediacy of a medication order and act upon it accordingly. | ___/___/___ | _____ |
| 6. The intern is aware of institutional policies and procedures for continuing medication orders, automatic stop orders, standing orders, formulary restrictions, and ancillary orders. | ___/___/___ | _____ |
| ***Pharmaceutical Care Plan*** | | |
| 1. The intern is able to develop a pharmaceutical care plan for safe and effective drug therapy by obtaining, interpreting, and using the following information:<br>a. Patient diagnoses<br>b. Prior medication history including allergies and sensitivities<br>c. Physicians' orders and progress notes<br>d. Nursing notes<br>e. Medication administration records<br>f. Laboratory data and diagnostic tests, reports, and consultations | ___/___/___ | _____ |
| 2. The intern is able to obtain a pertinent drug history from the patient and apply | | |

the information appropriately to the pharmaceutical care plan. ___/___/___ _____

3. The intern is able to use the pharmaceutical care plan developed for a patient to monitor the patient's drug therapy for appropriateness, efficacy, and adverse effects and be able to correct drug-related problems. ___/___/___ _____

***Order Processing, Dispensing and Control***

1. The intern is able to select the correct product from the pharmacy inventory and properly prepare and label the medication. ___/___/___ _____

2. The intern is able to accurately dispense and maintain all necessary records for controlled substances, in accordance with current state and federal laws, and institutional policy. ___/___/___ _____

3. The intern knows federal and state regulations as well as institutional policies and procedures for dispensing investigational drugs and their proper handling, storage and record keeping. ___/___/___ _____

4. The intern is able to perform and document the necessary calculations and perform the required technical and compounding skills to produce a pharmaceutically-elegant product. ___/___/___ _____

5. The intern understands the appropriate principles of aseptic technique and protection from cytotoxic exposure. The intern demonstrates these principles when compounding, labeling and dispensing intravenous admixture products. ___/___/___ _____

6. The intern is able to appropriately dispose of outdated, discontinued or recalled drugs, controlled substances, needles and syringes, and cytotoxic agents. ___/___/___ _____

7. The intern knows the correct use and maintenance of equipment for compounding and administering parenteral products, such as: infusion devices, administration sets, pumps, vertical and horizontal laminar air flow hoods, filters, and automated compounding devices. ___/___/___ _____

***Drug Information and Consultation***

1. The intern is able to effectively communicate all information necessary to encourage proper use and storage of the medication. This includes the importance of compliance with directions, and precautions and relevant warnings. The intern routinely verifies that the patient understands this information ___/___/___ _____

2. The intern is able to effectively select and use appropriate references to accurately answer drug information requests, and/or refers the questions to another source for response. ___/___/___ _____

3. The intern is able to effectively communicate drug information and provide drug-related "In-Service" presentations to pharmacists and other health care providers. ___/___/___ _____

4. The intern is able to evaluate the urgency of a poisoning or overdose situation, supply general information on the initial treatment, and refer the problem to the nearest poison information center if necessary. ___/___/___ _____

***Administration***

1. The intern knows the institution's policy and procedures pertinent to the pharmacy, including:
   a. Pharmacy and Therapeutics Committee structure and function
   b. Drug formulary management
   c. Adverse drug reaction reporting system
   d. Drug product selection, purchasing, and recall procedures
   e. Institution's implementation of federal and state regulations and JCAHO standards
   f. Medication errors and incident reports
   g. Hospital information system (computer network) ___/___/___ _____

2. The intern is able to discuss the scope of pharmacy services within the institution, and effectively communicate with other professionals, ancillary departments, and committees (e.g., hours of operation, nursing units served, dispensing of emergency order, etc.). ___/___/___ _____

*I certify, under penalty of perjury, that all objectives I have initialed have been met. To the best of my knowledge, the experience thus gained by this applicant has been predominantly related to the practice of pharmacy, as required by law.*

| Preceptor's Name | Initials | RPh # | State | Date |
|---|---|---|---|---|
| Preceptor's Name | Initials | RPh # | State | Date |
| Preceptor's Name | Initials | RPh # | State | Date |
| Preceptor's Name | Initials | RPh # | State | Date |

*Disclosure of your social security number is mandatory. Business and Professions Code section 30 and Public Law 94-455 (42 USCA 405(c)(2)(C) authorize collection of your social security number. Your social security number will be used exclusively for tax enforcement purposes of compliance with any judgement or order for family support in accordance with section 11350.6 of the Welfare and Institutions Code, or for verification of examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security number, your application for initial or renewal license will not be processed AND you will be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

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*AGENDA ITEM G*

THE AMERICAN COUNCIL ON PHARMACEUTICAL EDUCATION
20 North Clark Street, Suite 2500 • Chicago, Illinois 60602-5109 • www.acpe-accredit.org
312/664-3575 • FAX 312/664-4652

February 28, 2003

Dear Colleague:

As you have been notified, in response to a request from the Council on Credentialing in Pharmacy (CCP), the Board of Directors of the American Council on Pharmaceutical Education (ACPE) has agreed to initiate **a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training**. The decision was taken at the Council's board meeting held this January. ACPE is the national agency for the accreditation of professional degree programs in pharmacy, and providers of continuing pharmaceutical education. Further information about ACPE and its operations can be found on our website www.acpe-accredit.org. ACPE is asking for your feedback on this important process. The current diversity of qualifications, knowledge, responsibilities and regulation of pharmacy technicians will create both challenges and opportunities as the profession seeks to envision the proper quality assurance process for technician education and training. **ACPE recognizes the need to initiate the dialog with no pre-conceived ideas regarding the final outcome**. For the details on providing ACPE your thoughts on this issue, please continue…

**Invitation to Comment**

ACPE invites your organization to submit written comments and suggestions that you feel should be taken into consideration as the profession explores the issue of pharmacy technician education and training. We would also request that you publicize this request for comment to your relevant constituencies. We are seeking input from as wide an audience as possible. This invitation to comment has been sent to pharmacy organizations and foundations, colleges and institutes offering pharmacy technician training programs, schools and colleges of pharmacy, providers of continuing pharmacy education, and credentialing and accreditation agencies involved with pharmacy technicians. Individuals are also invited to comment.

For the purposes of the initial comment period, we request that written comments be submitted **as soon as possible but no later than October 31, 2003** to allow adequate time for the compilation of a summary before ACPE's January 2004 board meeting.

/cont'd

**Open Hearings**

The first in a series of open hearings is scheduled to take place at the annual meeting of the American Pharmaceutical Association in New Orleans, LA on Monday March 31, 2003. If you would like ACPE to convene an open hearing at one of your meetings, please contact us so that we discuss this further with you. Details of future open hearings will be publicized as and when arrangements are finalized.

**Background Materials**

The recently published White Paper on Pharmacy Technicians, endorsed by the 12 pharmacy organizations of CCP, identified several outstanding issues relating to pharmacy technicians. Many of the issues raised in the White Paper were further discussed at a summit on pharmacy technicians in May 2002. Along with the White Paper, the summit report is recommended reading. The references for these documents are on the enclosure.

On behalf of ACPE, we thank you for your contribution to this important exercise. We look forward, with your help and input, to identifying the best course of action, not only for the profession of pharmacy, but also for the promotion of public health and the better use of medications.

Please contact us if we can be of further assistance.

Yours truly,

Peter H. Vlasses, Pharm. D.

Peter H. Vlasses, PharmD, BCPS, FACCP
Executive Director

Mike Rouse, BPharm (Hons), MPS
Assistant Executive Director
International & Professional Affairs

**Enclosed**: ACPE Invitation to Comment: Education and Training of Pharmacy Technicians

# The American Council on Pharmaceutical Education

## Invitation to Comment: Education and Training of Pharmacy Technicians

Following a request from the Council on Credentialing in Pharmacy (CCP), the American Council on Pharmaceutical Education (ACPE) has agreed to initiate a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training.

### Outline of the Process

Subject to a decision on whether or not to proceed with the development of national standards *(a decision which is expected to be taken in January 2004)*, ACPE believes that the whole process, from initiation to implementation, could take about three years. In broad terms the process will be as follows:

Year 1 (2003) ACPE will solicit written comments from pharmacy organizations and individuals and convene a series of open hearings. Comments submitted will be analyzed and summarized.

Year 2 (2004) *If warranted based on the feedback of the previous year*, ACPE will develop and publish a draft set of competency-based standards for pharmacy technician education and training. ACPE will solicit comments on the draft standards from pharmacy organizations and individuals in written form and in open hearings meetings, and re-draft the standards based on feedback received.

Year 3 (2005) ACPE will invite final review of the revised standards by the professional organizations, adopt the standards and initiate the process to accredit pharmacy education and training programs. ACPE will initiate a process for the development of "distinctive standards" for continuing education providers that wish to conduct accredited continuing education programs for pharmacy technicians.

### Invitation to Comment

ACPE is hereby inviting organizations and individuals to submit written comments and suggestions that they feel should be taken into consideration as the profession discusses this issue. Official documents and policy statements are also welcome. Comments may cover any area relevant to pharmacy technicians, but ACPE requests that respondents focus on the questions and areas listed below. It is anticipated that other discussions, which are outside of ACPE's specific terms of reference, may also be required. When compiling your comments, please consider the future of pharmacy technicians, not only the present.

**Questions to be Considered**

1. Definition

   The 2002 White Paper[1] lists the following definition:

   *A pharmacy technician is an individual working in a pharmacy setting who, under the supervision of a licensed pharmacist, assists in pharmacy activities that do not require the professional judgment of a pharmacist.*

   Is this definition appropriate and adequate? How could it be improved to better define pharmacy technicians, and reflect what is happening and required in practice, both now and in the future?

2. Levels of Pharmacy Support Personnel*

   Should different levels of pharmacy support personnel (* not including clerical, accounting and housekeeping functions) be defined? If so, what should these be? What additional definition(s) would be applicable?

3. Roles, Responsibilities and Competencies of Pharmacy Support Personnel

   For each level of pharmacy support personnel identified in #2 above, describe the roles, responsibilities and required competencies.

4. Education

   *Education involves a deep understanding of a subject, based on explanation and reasoning, through systematic instruction and teaching.*[1]

   For each level of pharmacy support personnel identified in #2 above, describe the required education, including eligibility requirements and continuing education.

5. Training

   *Training involves learning through specialized instruction, repetition and practice of a task, or series of tasks, until proficiency is achieved .*[1]

   For each level of pharmacy support personnel identified in #2 above, describe the required training, including eligibility requirements.

6. Quality Assurance of Pharmacy Technician Education and Training

   For the education and training of pharmacy technicians described in #4 and #5 above, what is/are the most appropriate system(s) of quality assurance?

# *AGENDA ITEM H*

June 6, 2003

TO: Licensing Committee, State Board of Pharmacy
Patricia Harris, Executive Officer, State Board of Pharmacy

FROM: Gale W. Moniz, R.Ph., FSVHP, Dipl. ICVP
Pharmacist-in-Charge, Veterinary Medical Teaching Hospital Drug Room

RE: Draft for scope and structure for a new licensure program for pharmacies associated with Veterinary Medical Clinical Training Facilities

*Site*

Licensure would apply to pharmaceutical services within a Veterinary Medical Clinical Training Facility and its various campus locations. It pertains to a drug room where dangerous drugs (including controlled substances) and devices are managed for use on animal patients of this practice setting. The license shall apply to faculty (visiting and tenured), veterinary practitioners, veterinary students, veterinary residents and animal health technicians employed at the facility. These individuals must be performing clinical duties as part of their training to achieve a Doctorate in Veterinary Medicine (DVM) or advanced veterinary medical degree, or to perform their clinical research or teaching duties. These individuals are exempt from licensure through the Veterinary Practice Act (B&P Code Section 4830(d-e)). The facility is accredited through, and maintains standards according to, the American Association of Veterinary Medical Colleges, and the American Animal Hospital Association.

*License:*

The license shall cover all Veterinary Medical Clinical Training Facility campus locations, as well as ambulatory "field service" trucks. The various locations maintain drug supplies to facilitate patient therapy in remote areas. Veterinarians or pharmacists practicing in these facilities are responsible for the assurance that the drugs are used appropriately. Veterinarians or pharmacists in the facility must determine what may be dispensed or provided, using an order (either written, oral, or electronic), based on guidelines from the pharmacist-in-charge.

*Drug dispensation:*

A chart order or prescription order provided to the pharmacy will be used to obtain drugs for patients in the hospital locations. If a chart order is written, animal health technicians, veterinary students, veterinary residents, and/or veterinary faculty may obtain drugs, and subsequently administer them to the animal patients.

A formal prescription must be written and filled in the pharmacy for any medication to be provided to go home with the client owner of the animal patient. These prescriptions would be handled in a manner similar to that employed in a community pharmacy. Additionally, prescriptions for food production animals will be required to have withdrawal times and dairy labeling requirements pertaining to lactating and non-lactating cattle indications.

*Access to prescription drugs:*

Drugs and devices may be stocked in the various locations of the Veterinary Medical Clinical Training Facility for use by practitioners as needed. The use of dangerous drugs on animal patients of the facility (not to include research or didactic teaching efforts) is considered to be under the control of the pharmacy. The pharmacist-in-charge works directly with veterinary practitioners and other veterinary personnel to assure timely appropriate access to drugs and devices, and maintains policy and procedures to assure safe handling and labeling of dangerous drugs. All drugs are purchased through ethical and appropriate sources.

Because the teaching and training must align itself with a typical veterinary practice, non-pharmacist staff (pharmacy technicians and other trained staff) may prepare and label drugs for use on site, or off premise drugs, and/or devices for use on animal patients. Those drugs and/or devices can be provided directly to veterinarians, veterinary students and animal health technicians pursuant to a chart order or formal prescription written by a veterinarian. Pharmacy technicians and other trained individuals practicing in a Veterinary Medical Clinical Training Facility can continue working while the pharmacist or veterinarian is elsewhere. The drugs prepared for the animal patients are the responsibility of the ordering veterinarian and will not be administered to the animal patient without being checked by a pharmacist, veterinarian, veterinary student, and/or animal health technician.

In order to meet the immediate needs of animal patients 24 hours a day, 7 days a week, there shall be a supply of drugs and devices within the facility, accessible without entering the pharmacy or other drug area. Strict policy and procedure will be provided to delineate the designated veterinarians and animal health technicians who are authorized to access these drugs and/or devices. Automated dispensing machines can be employed to help manage stock and maintain records of drug and/or device use from these machines.

June 6, 2003

TO: Licensing Committee, State Board of Pharmacy
Patricia Harris, Executive Officer, State Board of Pharmacy

FROM: Gale W. Moniz, R.Ph., FSVHP, Dipl. ICVP
Pharmacist-in-Charge, Veterinary Medical Teaching Hospital Drug Room

RE: Background and justification for a new licensure program for pharmacies associated with Veterinary Medical Clinical Training Facilities

**Background**

Prior to the opening of the Veterinary Medical Teaching Hospital (VMTH) as an academic fourth year clinical training facility for veterinary medical students in the School of Veterinary Medicine at the University of California – Davis, the use of drugs in veterinary medicine was modest, and veterinary practices were small in nature (typically a single veterinarian practice). Veterinarians ordered, managed, and dispensed their own drugs. The VMTH, opened in 1970, was the first to consider the importance of drug management, and to incorporate this unique educational emphasis into the program by hiring a pharmacist, and centralizing the pharmacy function. Even though the functions performed at the VMTH pharmacy parallel many of those found in human healthcare settings, the emphasis is quite different. The veterinary drugs are used in the clinic (a combination of a veterinary clinic and a full service animal hospital) or are dispensed for home or farm administration to the animal patient. Those dispensed for use off the premises are dispensed directly to the veterinarian, or to the animal health technician or senior veterinary student on the case, under the direct supervision of the veterinarian. This means the **veterinarians are directly responsible for the drugs** being provided to the client for their animals to use. The VMTH is an academic veterinary clinical training facility as well as a very large, complex veterinary practice. The standard of practice in Veterinary Medicine, as described in the Veterinary Practice Act, is the provision of drugs to a client **by the veterinarian**, through their practice, subsequent to a veterinarian-client-patient relationship being established.

By 1988, it was recognized that the VMTH had evolved into a very diverse and complex practice. It was also apparent that the centralized pharmacy function was recognized to be extremely important relative to (1) consistency of pharmaceutical practice, (2) having the most current pharmaceutical information available to our clients (by way of the veterinarians), (3) improving the students' education relative to the most current pharmacy practice and regulations, and (4) having the ability to order the appropriate drugs for such a complex practice quickly and efficiently. These factors led VMTH management to the conclusion that the pharmacy activity could best be managed under licensure through the State Board of Pharmacy (BOP), rather than

under the auspices of the individual veterinarians and Veterinary Practice Act. At that time, the BOP determined that the closest fit for licensure was as a Drug Room. Although that solution did not address all the issues we face with proper handling and labeling of veterinary-label drugs, especially those dispensed to farms for use on food production animals, it seemed prudent at the time, and would allow us to practice as we were. The BOP recognized that this provided a much higher level of consumer protection (and education to veterinarians-in-training) than the Veterinary Practice Act model, simply because of the diversity and complexity of the VMTH practice, and its academic mission.

Subsequent to an inspection last summer, it was decided by the BOP that the Drug Room Permit was not an appropriate licensure, because the VMTH is not associated with a hospital licensed through the State Department of Health Services. We began looking to other existing licensing specifications (with an emphasis on hospital pharmacy) for a fit, and even worked with Paul Riches in an attempt to attach language to SB175 to change existing licensing requirements so that we could sculpt a solution in this way. After considerable efforts, it was decided that our unique practice setting (that of an academic veterinary practice, not a "human" hospital) and our lack of ability to comply with many areas of hospital pharmacy regulations, were indeed too sweeping to consider managing through an attachment to SB175. The only alternative we could see was to propose that a new section be added to the existing pharmacy regulations, and that this new "Academic Veterinary Pharmacy" section, spell out the necessary differences/exemptions from the existing (human) pharmacy regulations.

We recognize that this is not a trivial undertaking, but believe the time is right to address this, in part because of the increasing profile of veterinary label drugs, and in part because of the recognized importance of adequately regulating academic veterinary pharmacy activity within its proper context, rather than under the human hospital pharmacy context (or Veterinary Practice Act context) that currently only exists. While the VMTH at UC Davis is the current focus of this new legislation, other academic veterinary practice settings in the state are emerging. (e.g., University of California Veterinary Medical Center-San Diego, and Western University's new School of Veterinary Medicine), and how they elect to manage their pharmacy activities, will undoubtedly be determined in large part by what body of law with which they must comply. Taking an even broader view, many of our colleagues practicing academic veterinary pharmacy in other veterinary schools across the nation have expressed similar challenges with their respective state laws' licensure categories. By amending our regulations to include a section specific to academic veterinary pharmacy, we would be providing a valuable model for other states to follow.

**Public Harm**

The Licensing Committee is already fully familiar with the benefits of pharmacists' intervention in providing drug therapy to people, and the same benefits hold true for the medical care of animal patients. We will not re-enumerate those benefits here. Animal patients of the VMTH (approximately 33,000 per year) have benefited from pharmacists' intervention in patient care under its Drug Room authorization, and since this is no longer possible, there will be significant public harm if new legislation is not crafted, forcing the VMTH to practice under the auspices of the Veterinary Practice Act.

The **direct** public harm will be in the form of less real control over the inventory of dangerous drugs (including controlled substances) currently managed by the pharmacists, as these would

instead be managed by a plethora of veterinary practitioners, within the institution. The pharmacist-in-charge at the VMTH is the registrant on the DEA licenses for the facility, and this responsibility includes the maintenance of an immense array and quantity of controlled substances for use in animals for restraint and pain control (unparalleled in the private practice setting). This extends to the management and control of automated dispensing machines, employed to assure compliance with DEA regulations with regard to storage, handling and documentation for these drugs. Without the current pharmacists' role and authority in place (and it cannot exist with that authority if exclusively under the Veterinary Practice Act), control clearly would diminish. Direct public harm would also occur for VMTH patients because quality assurance programs would be stripped of their effectiveness without pharmacist intervention. While there are many more probable examples of increased potential for public harm, the last one we'll cite here is the fact that VMTH pharmacy personnel perform the functions of a Veterinary Food Animal Drug Retailer to assure proper handling and labeling of drugs provided for food producing animals in order to avoid drug residues in food consumed.

The **indirect** public harm, we believe, is of even greater significance. Such harm would come, first and foremost, from the diminished presence of pharmacists in the education of California's graduating veterinarians every year. The daily importance of teaching and guidance of drug management and therapeutics to DVM students and residents by our pharmacists simply cannot be overstated. The veterinary profession has embraced the importance of this teaching emphasis, and the present environment is the **only** one in which it can occur to this degree. The potential for public harm caused by the next wave of veterinarians who could be less adequately trained and sensitive to drug issues is very real, and is the driving force behind our request for this new body of legislation.

The profession of veterinary pharmacy, as a unique subset of the pharmacy profession, is now recognized across the nation. With the increasing recognition and importance of pets as "family members", the importance of this subset has also grown. Specialty certification programs for veterinary pharmacists are emerging nation-wide (International College of Veterinary Pharmacists, a certification program through the Society of Hospital Pharmacists), and will undoubtedly have a mitigating effect on the potential for public harm if such programs are supported. This ultimately requires the proposed new body of law be attached to the current pharmacy regulations.

**Lack of Ability to Comply With Current Pharmacy Regulations**

In the "Background" section of this request, we introduced the fact that, unlike human medicine, the doctor (veterinarian) is ultimately responsible for the veterinary drug use in the VMTH, just as they are in a private veterinary practice setting (required by the Veterinary Practice Act). This fact has several implications that make it impossible to comply with the current body of (human) hospital pharmacy regulation, despite the fact that most of the existing regulations are as important to the veterinary patient as they are to the human patient, and should be expected and enforced in both environments. Included in the implications that make it very difficult or impossible to comply, are the facts that:

- Animal health technicians (AHT's) handle medications, including controlled substances, under the direction of a veterinarian (resident or faculty), as they would in a private veterinary clinic. AHT's function in veterinary medicine much the same as nurses do in the "human" setting.

- Field Service trucks are stocked with medications and travel to remote areas to provide veterinary services. All activities are under the direct supervision of the veterinarian on duty that day, who is responsible for the maintenance of accurate records in their truck. This service is provided 24/7/365, and small stocks of veterinary drugs are made available to restock the trucks between farm visits. Veterinary drugs supplied to ranchers and animal caregivers are labeled by the veterinarian for use on the premises to treat livestock and companion animal patients.

- The Zoological Medicine Service handles immobilization medications, including but not limited to, some of the most potent narcotic agents in schedule II (e.g., Carfentanil). The veterinarians on that service are responsible for the appropriate use of these agents and the safety of individuals handling them. They order, manage inventories, etc, just as a veterinarian in a zoo would do.

- Patient counseling: Clients are counseled on veterinary drugs by the veterinary students, veterinary residents, AHT's and/or veterinary faculty, just as is the case in private veterinary practice. This is an essential part of their training.

- Pharmacist functions: The VMTH pharmacists perform managing, didactic teaching, and training functions. We handle all drug information questions for veterinarians (in-house as well as world-wide), teach and train veterinary and pharmacy students and residents, assure controlled substances are handled properly, and assure that labeling laws are upheld...all in a supporting role to the veterinarian. VMTH pharmacists do not function "at the bench", checking prescriptions (that is done by the veterinarians), or in a patient consulting capacity (clients are consulted by veterinarians as they are in a private veterinary practice).

- Technician to pharmacist ratio: Economic constraints prohibit the academic veterinary pharmacy setting from meeting the prescribed human hospital pharmacy ratio for technicians to pharmacists, especially when the 24 hour needs of the clinic operations are considered. Further, with the pharmacist shortage, it would be impossible to successfully recruit for the positions even if the finances could be obtained.

- Pharmacy technician functions: The VMTH pharmacy technicians perform their duties under the direction of the veterinarian on the case. They are strictly in place to assist the veterinarian in getting the drugs labeled correctly for dispensing to animal inpatients and/or outpatients of the VMTH.. We fill approximately 9000 inpatient animal orders monthly.

- 24/7/365 coverage for services: The veterinarians are responsible for the proper handling of drugs after hours, as they are in a private veterinary practice. Much in the way of teaching, training, and policies and procedures to assure this is done appropriately, has been provided, but again, the veterinarians have the ultimate responsibility. After hours, any drug, compounded product, injectable preparation (including TPN and chemotherapeutics prepared by trained individuals), etc., must be made available to the veterinarian in order to treat their emergency patients. This is accomplished through the use of assistants who function under the direction of the veterinarian. To close the pharmacy after hours would result in the veterinarians, themselves, maintaining multiple stocks of drugs for after hours emergency needs, and would be a huge step backwards in drug control and timely therapeutic treatment.

- The VMTH is not a "Licensed Healthcare Facility". We are not regulated through the State Department of Health Services. We are accredited through, and maintain standards according to, the American Association of Veterinary Medical Colleges (AAVMC), and the American Animal Hospital Association (AAHA). The Veterinary School and the VMTH provide for the clinical teaching and training of veterinary students and residents. In fact, the VMTH's actual University name is the Veterinary Medical Clinical Training Facility (VMCTF).

- Radioactive drugs are handled solely through the Radiology unit under the direction of a veterinarian. Pharmacists are not involved in any aspect of this endeavor.

- The VMTH pharmacy provides veterinary drugs for food animals in our clinic. This means that the veterinary food animal drug retailer laws would need to be visited.

- VMTH stock is not separated for inpatient and outpatient dispensing because that is not required in a veterinary practice. Compliance with this requirement would be impossible in light of the nature of veterinary practice needs.

These are the areas of existing regulation that we expect to address in the proposed new section specific to academic veterinary pharmacy.

**Summary**

We hope you will be convinced, as we are, that this new body of legislation is not only needed now, but also for future advancements related to veterinary pharmacy, not only in the State of California, but nation-wide. A draft suggesting the scope and structure for a new licensure program for pharmacies associated with veterinary medical clinical training facilities is attached to this request. The legislative arena is one that is completely foreign to us, so the Committee's (and ultimately the Board's) support and advice related to how we could best proceed is what we seek. Thank you so much for your consideration of our request.

# *AGENDA ITEM I*

**State of California** **Department of Consumer Affairs**

# Memorandum

**To:** **Licensing Committee** **Date:** **June 11, 2003**

**From:** **Patricia F. Harris**
**Executive Officer**
**Board of Pharmacy**

**Subject: Request for Approval as an Accreditation Agency for Pharmacies that Compound Injectable Sterile Drug Products**

Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license. At the last meeting, the board approved Accreditation Commission on Healthcare (ACHC) as an accreditation agency.

The Community Health Accreditation Program (CHAP) is also requesting approval as an accreditation agency as authorized under current law. CHAP is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. CHAP currently accredits 35 pharmacies located in 14 states; currently there are 3 California pharmacies that are CHAP accredited and two that have applied.

CHAP provided documentation to respond to the 8 factors that the board adopted at its last meeting to guide it in its evaluation and approval of these accreditation agencies.

These factors are:

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 payors** – Recognition of the accrediting agency by

major California payors (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.

CHAP
COMMUNITY HEALTH ACCREDITATION PROGRAM

39 Broadway Suite 710 New York, NY 10006 tel: 212-480-8828 fax: 212-480-8832 web: www.chapinc.org

RECEIVED BY CALIF. BOARD OF PHARMACY
2003 JUN -6 PM 2: 35

June 5, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: Application for Board Approval under Senate Bill 293, Section 4127.1d

Dear Ms. Harris:

The Community Health Accreditation Program, Inc. (CHAP) is applying to California State Board of Pharmacy for approval to exempt pharmacies from licensure under requirements established by Senate Bill 293, Section 4127.1d of the Business and Professional Code.

Included is CHAP's response to the evaluation factors identified by the Licensing Committee as required in section 4127.1. CHAP supportive documentation is attached as Appendix I – III.

CHAP is a national non-profit accreditation organization established in 1965 as the first organization in the United States to accredit community-based health care organizations. CHAP currently accredits pharmacies in California as well as other States across the Country.

If possible, I request that the Board consider CHAP's application for approval at the July, 2003, Board of Pharmacy meeting.

Please contact me if you need further documentation.

Thank you for consideration of this application.

Sincerely yours,

Terry A. Duncombe, RN, MSHA
President & CEO

**APPLICATION TO THE CALIFORNIA STATE BOARD OF PHARMACY FOR APPROVAL TO EXEMPT PHARMACIES FROM LICENSURE UNDER REQUIREMENT ESTABLISHED BY SENATE BILL 293 (SECTION 4127.1D OF THE BUSINESS AND PROFESSIONS CODE)**

**SUBMITTED BY:**
**COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP)**
**39 BROADWAY, SUITE 710**
**NEW YORK, NY 10006**
**JUNE 5, 2003**

**Factor 1. Periodic Inspection**

The Community Health Accreditation Program, Inc. (CHAP) conducts a full comprehensive site visit to pharmacies at least once every three years. Every standard for Core, Pharmacy, and Infusion Therapy is assessed during these site visits. Based upon the performance of the pharmacy and the findings, particularly in the Quality Standards (Section II of each set of standards), the CHAP Board of Review may determine to require a return site visit within 6, 12, or 24 months to focus on and assess compliance with the required actions cited during the site visit. The Accreditation Process is described in the document, Introduction to CHAP Accreditation, which is included as Appendix I.

**Factor 2. Documented Accreditation Standards**

CHAP accredits compounding pharmacies. CHAP currently uses three sets of standards to assess pharmacies: Core (overall administrative standards), Pharmacy (service specific standards) and Infusion Therapy (limited to Infusion Pharmacies). The Standards are included as Appendix II. Each of the three sets of standards contain language further requiring compliance with State and Federal statues governing pharmaceutical practice. Each pharmacy is assessed during a site visit for compliance with CHAP standards as well as federal and state-specific regulations. In addition, CHAP standards are consistent with the professional standards of practice as defined by the American Society of Health System Pharmacy and published in Best Practices for Health-System Pharmacy, ASHP, 2002-2003 Edition, and referenced for assessment.

CHAP assesses standards in terms of "Met" or "Not Met." The standard must be met in full to be assessed as "Met." If any element of the standard is not met, the standard is assessed as "Not Met," and a "Required Action" is written for that Standard. Required Actions are actions which the organization is required to perform in order to achieve compliance with CHAP Standards. The Board of Review decision to accredit, deny accreditation or defer accreditation is based upon the number and types of Required Actions identified. CHAP does not use a scoring methodology for assessing compliance and determining accreditation decisions

An organization is **accredited** if the site survey findings provide evidence that the organization Is in substantial compliance with CHAP standards. An organization is **deferred** in initial accreditation based upon evidence that the organization is not in substantial compliance with

the CHAP Standards but has evidence that they possess the ability to come into substantial compliance within a reasonable time frame, not to exceed one year from the deferral date. A full site visit will subsequently be conducted to determine compliance with CHAP standards. An organization is **denied** initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards and lacks adequate structure and function to correct the deficiencies in a timely manner. The organization has the option of re-initiating the application process six months from the date of the initial site visit. Other Board of Review accreditation decisions include **formal warning** and **termination** which are delineated in the Introduction to CHAP Accreditation, Appendix II.

**Factor 3. Evaluation of Surveyor's Qualifications.**

CHAP requires pharmacy site visitors to have the following minimum qualifications:

1. Currently licensed Registered Pharmacist with a minimum Bachelor of science in pharmacy.
2. Five years experience in pharmacy management.
3. Current experience in community-based or infusion-based compounding pharmacy services.
4. Demonstration of strong analytical, consultative, conflict resolution, mediation and written and written and verbal articulation skills.
5.. Demonstration of experience with an accreditation process.
6. Successful completion of a CHAP Site Visitor Training Program and four practicum site visits.

CHAP currently has six pharmacy site visitors with professional pharmacy experience ranging from 5 – 40 years, with clinical management experience ranging from 5 – 23 years, with two holding Master degrees and one working on a Doctor of Pharmacy degree. Each one of CHAP's pharmacists is currently employed in active pharmacy services.

The CHAP Board of Review (BOR) has a pharmacist appointed by the Board of Directors. That pharmacist has a Doctor of Pharmacy and is responsible for reviewing and assessing Pharmacy Site Visit Reports to assure consistent citation of pharmacy standards. The BOR Pharmacist is also responsible for assessing new or revised standards as part of the BOR and recommending adoption to the Board of Directors.

**Factor 4. Acceptance by Major California Payors**

CHAP is accepted by all California payors as well as all national payors with the exception of one payor in Southwestern Pennsylvania.

**Factor 5. Unannounced Inspection of California Accredited Sites**

CHAP understands that the State Board of Pharmacy will conduct unannounced inspections of two or more California accredited pharmacy sites to assess for satisfactory compliance with California law and good professional practice.

**Factor 6. Board Access to Accreditor's Report on Individual Pharmacies**

CHAP provides a written report to each pharmacy following a site visit and review and determination by the Board of Review. Each of the pharmacies accredited by CHAP has a copy of the written report available on site. In addition, CHAP Core Standard CI.4a. requires an organization to have a written public disclosure policy that provides public disclosure of the accreditation report and other documents.

**Factor 7. Length of Time the Accrediting Organization Has Been Operating**

CHAP has been accrediting organizations since 1965. CHAP was the first national accreditation organization to accredit community-based health organizations in the United States and was the first organization awarded deeming authority by CMS (formerly HCFA) for home health in 1992 and for hospice in 1999. CHAP Pharmacy Standards are recognized by JCAHO as being comparable in definition and expectations.

**Factor 8. Ability to Accredit Out-of-State Pharmacies.**

CHAP currently accredits organizations throughout the United States, Hawaii and Puerto Rico and is able to accredit pharmacies regardless of state of operation.

CHAP currently accredits 35 Pharmacies located in 14 states. CHAP has 44 pharmacies that have applied for accreditation and are in the process of contract execution or currently undergoing the self-study process.

**Additional Questions:**

**1. What companies are accredited for Pharmacy by CHAP in California?**

Accredited since November, 2001:
Homecare Preferred Choice, Inc. dba Beverly Home Care Infusion Services, Monrovia
Homecare Preferred Choice, Inc. dba Beverly Home Care Infusion Services, Loma Linda

Accredited since October, 2002:
Children's Home Care, Glendale

Applied for Accreditation:
Factor Support Network Pharmacy, Inc., Camarillo
John Davis Company, Sacramento

**2. Is CHAP accreditation comparable to JCAHO ?**

JCAHO has completed an evaluation of CHAP standards which resulted in their recognition of general comparability between the standards of our two organizations.

**3. What is an example of an evaluation sheet and report?**

The CHAP Site Visitor Work Book is used for evaluating compliance with the CHAP Standards. A Board of Review Site Visit Report is generated from the commendations, recommendations and required actions cited in the Site Visitor Work Book. The Board of Review reviews the Site Visit Report and completes a Summary Data Collection Tool in order to assure a logical and focused review of Site Visit Reports and to promote consistency in the interpretation of site visit findings by each reviewer. Consistency in the interpretation of site visit findings by the Board of Review drives the decision making process. A sample of the Site Visitor Work Book, the Board of Review Site Visit Report format and the Board of Review Summary Data Collection Tool are included as Appendix III.

# INTRODUCTION

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# CHAP INTRODUCTION

## OVERVIEW AND HISTORY

The **Community Health Accreditation Program, Inc. (CHAP)** is an independent, non-profit accrediting body. It was the **first** accrediting body for community-based health organizations in the United States and was created in 1965 as a joint venture between the American Public Health Association (APHA) and the National League for Nursing (NLN). These organizations brought to fruition the futuristic view that accreditation was the needed mechanism for recognizing excellence in community health practice. In 1988, CHAP became a separately incorporated, non-profit subsidiary of the NLN under the CHAP name. In 2001, it was spun-off by the NLN and became an independent, non-profit corporation.

CHAP was granted "deeming authority" by the Centers for Medicare and Medicaid Services (CMS—formerly HCFA) in 1992 for home health, and in 1999 for hospice. This means that instead of state surveys, CHAP has regulatory authorization to survey agencies providing home health and hospice services, to determine whether they meet the Medicare Conditions of Participation (COPs).

CHAP accreditation is available to organizations providing the following services:

- Home Health
- Hospice
- Home Medical Equipment
- Home Pharmacy
- Infusion Therapy Nursing
- Private Duty Services (includes professional and paraprofessional services)
- Home Care Aide Services (for paraprofessional-only businesses)
- Public Health
- Supplemental Staffing Services
- Community Nursing Centers
- Community Rehab Centers

## *STANDARDS OF EXCELLENCE*

The CHAP accreditation process uses the CHAP ***Standards of Excellence*** which are driven by considerations of management, quality, client outcomes, adequate resources, and long-term viability. The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement
- Promote consumer satisfaction

- Promote positive client outcomes
- Meet community health needs in a cost effective and efficient manner
- Maintain the viability of community health practice nationwide
- Assure public trust in community-based services and products

CHAP is committed to assuring that home and community health care organizations adhere to the highest standards of excellence, and that providers maintain compliance with the current standards. The CHAP ***Standards of Excellence*** provide guidance and reality-based criteria for the evaluation of an organization. These criteria are based on four (4) key "Underlying Principles" (UP), which drive each set of the CHAP standards. Following are these principles:

I. The organization's structure and function consistently supports its consumer oriented philosophy, mission, and purpose.
II. The organization consistently provides high-quality services and products.
III. The organization has adequate human, financial, and physical resources to accomplish its stated mission and purpose.
IV. The organization is positioned for long-term viability.

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP continually reviews and updates the ***Standards of Excellence.***

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

**GOVERNANCE**

CHAP is governed by an independent, voluntary Board of Directors. Members of the Board of Directors represent consumers, purchasers, and providers, as well as experts in the home and community health care industry. Responsibilities of the Board of Directors include:

- Determining CHAP's philosophy, mission, and purpose
- Establishing its policies and planning for the future direction
- Assuring compliance with statutory and regulatory requirements
- Evaluating CHAP's performance in relation to its philosophy, mission, and purpose

**PHILOSOPHY**

*The CHAP Philosophy assures the availability of quality home and community-based health care through the voluntary commitment to accreditation by the applicant organizations.* This is essential as home and community health care become the centerpiece of the health care industry. It is CHAP's firm belief that the

accreditation process should clearly separate excellent organizations and programs from those meeting only minimal standards. CHAP further believes that standards should be:

- Driven by the goal of consumer protection
- Easily understood and administered
- An instructive tool that encourages a participative process for organizations
- Used to evaluate the total system of care, services, and products

### Mission

*The CHAP Mission is to provide leadership for enhancing the health and well-being of diverse communities.* This is achieved through the development of the ***Standards of Excellence*** which assure the management of ethical, humane, and competent care in home and community-based organizations. In addition, the development and dissemination of innovative products, services, and models of care, as well as the creation of partnerships, promote this mission.

### Purpose

*The CHAP Purpose is to develop and promote standards applicable to all types of home and community-based health service providers.* Providers range from individually-owned businesses to large corporations, for-profit and/or non-profit, public and private. To accomplish its purpose, CHAP:

- Provides an external, objective marker for organizations' consumers, demonstrating that they meet national standards of quality
- Provides consumer-oriented national standards for the full range of services and products available
- Conducts evaluations of providers and grants accreditation to those organizations meeting or exceeding CHAP standards
- Promotes the development and dissemination of new knowledge and products by encouraging on-going research
- Provides information to assure that purchasers and consumers have information readily available to make informed decisions

## Accreditation Process

### Eligibility for Accreditation

All home and community-based health care service providers are eligible to seek accreditation by CHAP. Applicant organizations must meet the following criteria:

- Have legal authority to operate
- Provide one or more of the services or product lines listed on page three
- Prepare and submit the required accreditation application documentation and fees on a timely basis

CHAP will accredit separate and distinct programs or services individually. CHAP recommends, however, that all home and community-based health care programs and services of an organization be included in the accreditation process.

### Accreditation Cycle

Organizations are accredited for a three-year cycle. A self-study and full site visit initiate the accreditation cycle. Site visits may be made in years 2 and 3 of the cycle, based upon the on-site findings and the Board of Review determinations.

### Fees

Accreditation fees are based on the size and complexity of an organization. An initial, non-refundable application fee is required at the time of the application. CHAP divides the accreditation fee into three annual payments. In addition to the annual fees, there is a charge for the standards and self study. A separate per diem charge is made to cover site visit expenses. The projected number of site visit days is determined according to the size, complexity, and number of locations of the applicant organization. No site visit will take place until the first annual fee payment has been made. Accreditation fees are due and payable in accordance with the following schedule:

- A non-refundable application fee is due with the submission of the application
- The first annual fee and charge for the standards and self-study are due with the submission of the signed contract
- The second and third annual fee payments are due on the anniversary date of the signed contract
- Site visit fees are billed at the completion of the visit and are due within thirty (30) days

At the conclusion of the formal Exit Conference, the lead site visitor completes the *Pre-Billing Report* and obtains the signature of an authorized official of the organization, which certifies the number of on-site days. The lead site visitor faxes the completed form to the CHAP office at the end of the last day on-site. The original is returned to the CHAP office with the *Site Visit Report* documents.

## The 4 Steps of the CHAP Process

### Step 1 – Application and Contract

The applicant organization completes the CHAP *Application for Accreditation* form and sends it with the application fee to CHAP. Upon receipt of the application, CHAP staff will:

- Determine the organization's eligibility for accreditation
- Establish a fee based on the information from the organization's application
- Estimate the number of site visit days necessary to assess the organization

An organization-specific contract is developed from the information in the comprehensive application. The contract delineates the duties and responsibilities of CHAP and the organization for a three year cycle. It locks in the annual fee and per diem rate for the number of anticipated site visit days. Two original contracts are sent to the organization for review and signature. The appropriate standards and self-study will be sent under separate cover. Both copies of the original signed contracts should be returned to the CHAP office within 30 days. One original contract will be returned to the organization, and one retained in the CHAP office after CHAP's President/CEO has signed them.

### STEP 2 – SELF-STUDY

The *Self-Study Report* is a unique and insightful self-evaluation tool, which addresses both the business and service aspects of the applicant organization. The *Self-Study Report* is due back in the CHAP office within six months of the date of the signed contract. CHAP staff will review the report and begin analysis of the content. (A one time three-month extension may be granted under qualifying circumstances.)

The purpose of the self-study is two-fold.

- It gives the organization the opportunity to complete a comprehensive internal evaluation in preparation for the site visit.
- CHAP uses the information submitted in planning the site visit process. An updated self-study should be submitted at the start of each accreditation cycle.

### STEP 3 – SITE VISIT PROCESS

The site visit team is comprised of health care professionals experienced in their respective fields. The composition of a site visit team is contingent upon the type of visit, size of the organization, and the complexity of services and products provided. The focus is to provide professional assistance while ensuring compliance with the CHAP ***Standards of Excellence*** and other regulatory requirements. Emphasis is placed on the "Underlying Principles."

### SITE VISITORS

"Site Visitor" is the term CHAP uses for those professionals who go on-site to organizations to assess the quality of the services and products provided. Lead site visitors are assigned whenever teams are used to conduct a site visit and have the primary responsibility for the site visit process overall. Lead site visitor qualifications include a minimum of five (5) year's senior management experience in a community-based health care organization and education at the master's level. The lead site visitor is responsible for coordinating all the activities of the site visit team and ensuring the timely completion of the *Site Visit Report*. In addition, the lead site visitor provides consultation to the organization.

Other site visitors are required to have five (5) years experience in a health care field that reflects the scope of care and services accredited by CHAP and have a bachelor's degree in a related specialty area. Nurses must have a BSN. Periodically, CHAP employs the use of "peer site visitors" who are selected from the management staff in other CHAP accredited organizations to participate in on-site activities.

Site visits may be conducted by one site visitor or by a team, based on the size, complexity, type of expertise needed and number of service delivery sites.

### Planning and Scheduling Site Visits

CHAP staff is responsible for the planning and scheduling of all site visits. All visits to Medicare home health and hospice organizations will be unannounced if the agency has chosen to use CHAP's deeming authority.

Organizations seeking accreditation, but not using CHAP's deeming authority from Medicare, may elect in writing to have prior knowledge of the date of the scheduled visit.

Organizations not visited on an annual basis will be required to submit annual progress reports or copies of internal annual evaluation reports.

Organizations designated for a return visit no sooner than 36-months, will be assigned to a pool from which 5% of the organizations will be randomly visited.

### Types of Site Visits

- **Initial Site Visit -** the first on-site visit made to an organization at the beginning of the accreditation cycle. (Year 1)
- **Annual Site Visit -** Site visits may be required in year 2 or 3 of the accreditation cycle depending on the outcome of the initial site visit (Newly certified Medicare home health agencies must have a site visit every year for three years, per Medicare regulations.)
- **Focus Visit -** site visit made in less than a year to follow-up with critical required actions
- **Complaint Investigation Visit** - site visit made to assess the validity of a complaint, usually related to patient care and safety issues.

Prior to a site visit, the organization completes the *Pre-Site Visit Questionnaire.* The questionnaire will be used to identify any changes made in the organization since the completion of the self-study, and to provide logistical information for site visitors (e.g., hotels, directions, etc.)

### The Entrance Conference

The lead site visitor announces the arrival of the CHAP site visit team and requests a meeting with the CEO and designated members of the administrative team. The purpose of this Entrance Conference is to:

- Demonstrate the preparedness of the team to conduct the site visit in a knowledgeable and organized manner
- Facilitate a professional and positive experience for the organization during the site visit
- Explain and plan the site visit activities and time frames

- Inform the organization about the materials, documents, and statistical information needed by the site visit team
- Engage all levels of the staff in the accreditation process
- Explain the consultative component of the site visit
- Establish the time, place and participants for the Exit Conference

At the Entrance Conference the (lead) site visitor will explain the responsibilities of the applicant organization, which include:

- Orienting site visitor(s) to the physical plant
- Introducing site visitor(s) to key staff
- Designating a primary contact person to work closely with the site visitor(s)
- Providing reasonable workspace for the site visit team
- Notifying clients and obtaining verbal permission for the home and service site visits
- Transporting site visitor(s) to home and service site visits
- Providing directions for travel to remote service sites
- Responding in a timely manner to requests from site visitor(s) for accreditation related documents and statistical data
- Arranging for interviews with key personnel and governing body member
- Arranging for observational experiences for site visitors
- Providing copies of video/audio taping of the Exit Conference at the close of the site visit

### Client Visits

Site visitors make visits to clients receiving care and services in the home and/or community-based settings. The purpose of these visits is to:

- Verify that the care, services, and products provided by the applicant organization meet CHAP standards
- Validate that the care, services, and products provided are consistent with the organization's policies and professional practice standards
- Assure that direct and contracted care, complies with the clients' plan of care/services
- Determine the clients' satisfaction with the plan of care/services

### Selection of Client Visits

On the first day of the site visit, the organization will provide a list of clients scheduled for visits that week. The site visitor will select a random sample of clients to be visited, taking into consideration diagnosis, payer source, service mix, and willingness of clients to allow these visits. For large organizations with multiple service sites, other considerations include travel time, distance, and previously visited sites.

### Permission for Client Visits

The organization contacts clients and receives verbal approval for the visit prior to the site visit. The purpose of a client visit is to observe the activities and interview the

client/representative in a non-disruptive manner. The site visitor is responsible for obtaining written approval from the client or client representative using the CHAP *Consent for Home Visit* form for home visiting and/or the CHAP *Consent for Home/On-Site Visit* form for public health site visits. A copy of the signed consent is distributed to the client and the organization. The original is returned to the CHAP office as a part of the *Site Visit Report*.

### Telephone Surveys

The site visitor may conduct telephone surveys of discharged clients and major referral sources to determine the level of satisfaction with the services and products provided by the organization. Sub-contractors may be contacted to address the level of compliance with the organization's policies and CHAP standards.

## The Exit Conference

The (lead) site visitor conducts an Exit Conference with designated members of the organization's staff. CHAP encourages the participation of management and supervisory staff as well as members of governing boards, advisory committees, and community members. The purpose of the Exit Conference is to:

- Applaud the agency for voluntarily seeking accreditation
- Extend appreciation to the organization for its cooperation with the site visit team
- Verbally report the findings of the site visit as they relate to the CHAP standards
- State the level of compliance with the *Medicare Conditions of Participation* for certified agencies through the CHAP deeming authority
- State the site visit team recommendation to the Board of Review
- Explain the function and accrediting authority of the Board of Review
- Provide an opportunity for the organization to ask questions or respond to the presentation
- Bring closure to the site visit

## Consultation

Additional benefits of accreditation by CHAP include: management consultation as part of the site visit, telephone consultation while preparing the self-study, access to a broad network of professional resources, and guidance to building intra- and inter-organizational collaboration and strength. Senior management and the (lead) site visitor will set the consultative agenda prioritizing areas for attention. Consultation will be provided at the conclusion of the Exit Conference.

## Step 4 – Determination of Accreditation Status

The *Site Visit Report* is the legal document that states the organization's level of compliance with CHAP standards. The *Centers for Medicare & Medicaid Services* (CMS) forms become a part of the *Site Visit Report* for home care and hospice organizations that have elected to receive Medicare certification through the CHAP deeming authority.

## Board of Review

The Board of Review (BOR) is the external body authorized by the CHAP Board of Directors to review and analyze site visit reports and make decisions regarding the accreditation status of applicant organizations. The BOR is comprised of senior management and quality specialists from CHAP accredited organizations, and industry experts. The actions taken by the BOR are based on the *Site Visit Report* from the site visit team that assessed the organization on-site. The determination of the accreditation status, and any follow-up actions required of an organization, is based on the "required actions" and "recommendations" of the site visit team. Careful deliberation of the *Site Visit Report* and review of other documents form the basis of the accreditation decision. Responsibilities of the BOR include:

- Reviewing site visit reports and progress reports
- Analyzing report data for relevance to the CHAP standards with particular emphasis on "commendations" and "required actions"
- Making objective accreditation decisions based on the site visit team recommendations and the results of the BOR analysis
- Documenting BOR findings on the *Board of Review Summary* form for each report reviewed
- Determining time frames for progress reports, focus visits, and next site visit using survey frequency guidelines
- Making recommendations to the Board of Directors and CHAP administration regarding accreditation policies, procedures, and practices
- Maintaining organizational information in a strictly confidential manner

Following the BOR session, CHAP staff complete the internal processing of the reports. Written notification regarding the final accreditation decision will be sent to the organization within 4-6 weeks following the BOR meeting. CHAP retains accreditation reports and related documents for two accreditation cycles or six (6) years. Possible Board of Review determinations include:

- Accreditation
- Accreditation with Required Actions
- Accreditation with Required Actions and a Progress Report Due
- Accreditation with Required Actions, a Progress Report Due, & follow-up Focus Visit
- Defer Accreditation (initial accreditation only)
- Formal Warning (continued accreditation only)
- Deny Accreditation (initial accreditation only)
- Withdrawal of Accreditation (continued accreditation only)

The organization may call the CHAP office to receive its accreditation outcome. The details of the findings and follow-up actions required will be outlined in the letter of notification. Organizations should receive their letter of notification 4 to 6 weeks following the BOR meeting.

### RECONSIDERATION

The applicant organization has the right to request a reconsideration of the findings of the BOR. This process begins with verbal notification to the Vice President Accreditation, followed by written documentation from the organization delineating its issues and concerns, within ten (10) working days. The BOR will review and evaluate the request at their next meeting, and issue a written report of their decision and findings.

### APPEAL

The applicant organization then has the right to appeal the findings of the BOR to the Appeal Panel, if it is still dissatisfied with the accreditation determination. The process is similar to the request for reconsideration. Again, it begins with verbal notification to the Vice President Accreditation, followed by written documentation from the organization explaining its rationale, within ten (10) working days from the initial call.

The Accreditation Appeal Panel is a committee of the CHAP Board of Directors and, as such, is appointed by the Chair of the Board of Directors. It is comprised of four members of the Board of Directors, at least two of whom have direct home or community-based health care knowledge and management experience, and at least one consumer representative. The presence of at least three members is necessary to conduct a meeting of the Appeal Panel. A vote that indicates agreement among a majority of those in attendance and voting determines a decision. Decisions of the Appeal Panel are final. Responsibilities of the Accreditation Appeal Panel include:

- Reviewing data regarding the appeal, (e.g., *Self-Study Report, Site Visit Report, Board of Review Summary*, and the organization's written documentation of concerns and issues)
- Conferring with appropriate individuals in order to obtain information relative to the appeal (e.g., site visitor, Board of Review member, and/or organization representative)
- Determining whether the decision of the BOR is substantiated by the data submitted
- Ruling to affirm, reverse, or change the document or send back the *Site Visitor Report* to the Board of Review for re-consideration, and specifying in writing the reasons for the ruling.

# CHAP Basics

THERESA S. AYER, MS, RN, CNAA

**Editor's Note:** *As home care and hospice agencies increasingly seek accreditation from the Community Health Accreditation Program (CHAP)— until recently a subsidiary of the National League for Nursing—it is important that* Home Healthcare Nurse *keep our readers aware of various aspects of this program. Starting with this column in our first issue of 2002,* HHN's *Accreditation Strategies column will share timely information about both CHAP and the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) on an alternating basis. Readers who have specific questions and concerns or a topic they would like discussed in this column on either of these accreditation programs should contact the Editor at chump@homehealth.win.net or via phone: (502) 339-9005.*

## History

The Community Health Accreditation Program (CHAP) began accrediting home health agencies in 1965 as a division of the National League for Nursing. In 1987, it became a subsidiary incorporated with the CHAP name. The next evolution occurred in 2001, when in mutual recognition of the diverging goals and missions of the National League for Nursing and CHAP organizations, CHAP was spun-off as a totally separate nonprofit corporation.

Throughout the last 34 years, the CHAP mission has been to provide leadership for the evolving home care community with a focus on the consumer and community needs. CHAP began with a focus on home health, at the same time the new Medicare reimbursement for this service began in 1965. Its initial goal was to assure quality home care as the service shifted from primarily maternal-child health to a focus on the elderly.

Always consumer oriented and driven to focus on the needs of the consumer, consumers have consistently served on CHAP's Board of Directors and Board of Review. In addition, these Boards have included representatives from business, health insurance, and accredited organizations to assure that CHAP Standards and processes stay current and relevant to the types of services being accredited. With this consumer focus, and in recognition of changing and evolving consumer needs, CHAP has added accreditation for many other community-based health services over the years and now accredits community-based organizations providing services in 11 different areas.

**CHAP views accreditation as a process and not an event; it focuses on how the agency looked during the last site visit, how it has since evolved and improved, and its plans for future enhancements.**

## Deemed Status

CHAP was the first accrediting body to receive Home Health Deeming Authority from HCFA (now CMS) in 1992, and renewed in 1999 as well as being first to receive Deeming Authority for Hospice also in 1999. "Deeming Authority" means that the federal government assures that CHAP's Standards of Excellence meet or exceed the government's own requirements for Medicare certification. Therefore, CHAP may evaluate home health and hospice organizations under the CMS Conditions of Participation and regulations for both home health and hospice in lieu of state surveyors conducting a survey. Therefore, CMS states that agencies meeting CHAP standards are "deemed" to have met CMS requirements.

In 1996 the Joint Commission entered into a cooperative accreditation agreement with

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**Figure 1. CHAP Accredits Organizations That Provide the Following Services:**

- Home Health
- Hospice
- Home Infusion Therapy
- Pharmacy Services
- Home Medical Equipment
- Private Duty
- Public Health Services
- Community Nursing Centers
- Community Rehabilitation Centers
- Home Care Aide Services
- Supplemental Staffing

CHAP. This agreement was "designed to reduce the duplicative onsite evaluations of home care organizations in integrated organizations surveyed under the Joint Commission's Network Accreditation Program" (CHAP, 1996). In reaching this agreement, CHAP's accreditation processes were compared to those of the Joint Commission and were found to be comparable. CHAP and the Joint Commission maintain separate philosophies and approaches to accreditation, but the ultimate goals for each organization (i.e., quality patient care at home) are the same.

## The CHAP Accreditation Process

CHAP views accreditation as a process and not an event. Agencies must continually strive to improve their operations and outcomes, aiming for excellence. CHAP accreditation does not view an organization in just a snapshot, but is interested in how the agency:

- looked during the last site visit (survey),
- has since evolved and improved, and
- is planning for future enhancements.

More specifically, it looks for improvement in its systems and outcomes related to all its customers, internal and external. That is, improvements should be aimed at staff, physicians, and other referral services as well as patients.

At any time while working with agencies, CHAP seeks ways to contribute to the refinement of the organization's clinical operations, business practices, and achievement of positive outcomes. Therefore, CHAP is not interested in accrediting home care organizations that have the ability to just scrape through the accreditation process successfully, but rather, those organizations that express an ongoing commitment to quality improvement and positive outcomes.

## The Four-Step Accreditation Process

Accreditation by CHAP is accomplished through a simple, four-step process:

1. the application and contract process,
2. agency completion of a self-study,
3. a site visit, and
4. determination of accreditation status by the Board of Review.

## Standards

Accreditation standards are revised as needed when changes occur in service areas. In 2001, CHAP revised the Core, Home Health, and Hospice Standards of Excellence. CHAP has separate Standards of Excellence and Self-Studies for each type of service organization (see Figure 1), plus Core Standards of Excellence and Self-Study that are applicable to all types of organizations. All Standards outline the requirements for achieving CHAP accreditation.

For example, an organization with home health, hospice, and home medical equipment (HME) would complete one Core Self-Study for all three services plus the Home Health, Hospice and HME Self-Studies. The Self-Study is a tool an organization can use to guide it through a structured evaluation of its internal capabilities and quality of operations. Because it is an intensive self-examination that requires significant effort and time, CHAP allows 6 months for the completion of the Self-Study. It is a step-by-step guide for the self-assessment of administration, clinical services, and financial operations, and is beneficial to any organization seeking improvement.

Each set of these Standards and Self-Studies is divided into four sections based on four key, underlying principles (see Figure 2). These principles address the structure and function of the home care organization; the quality of its services and products; the adequacy of its human, financial, and physical resources; and its long-term viability. For example, Underlying Principle II (UP II) focuses on quality of services and products in every set of Standards and Self-Study. This section of the Core Standards contains criteria and elements related to:

- organizational policies and procedures;
- client access to care, services, and products;
- prioritization of care delivery;
- planning, implementing, monitoring, and evaluation;
- clinical records;
- total quality management; and
- health and well being of employees and clients (CHAP, 2001a).

This section of the Home Health Standards has a similar albeit more specific focus on home health quality. Specifically, Section II addresses:

- specific services,
- access to care and services,
- care coordination,
- home health-specific policies and procedures (requirements not addressed in the Core Standards),
- CLIA requirements,
- medication management,
- effectiveness of care, and
- telemedicine (CHAP, 2001b).

**CHAP prides itself on its consultative approach. While completing an objective organizational review, consultation is provided after the Exit Conference on any area that the organization or site visitors think would be helpful.**

## The CHAP Site Visit

The Site Visit Workbook used by CHAP visitors while in the agency again follows the same four principles. The lead site visitor, prior to beginning the site visit, reviews the Self-Study to begin understanding how the organization functions. The review of the Self-Study may also identify areas of concern that will receive extra scrutiny during the site visit. The site visitor(s) completes the on-site evaluation following the structured approach of the Underlying Principles.

The site visit includes Entrance and Exit Conferences and a review of various types of organizational records and activities (with a particular focus on clinical records and home visits for all services provided). CHAP prides itself on its consultative approach to this evaluation. While completing a fair and objective review of the organization, consultation is provided after the Exit Conference on any area that the organization or site visitor(s) believes would be helpful.

The site visitors prepare the site visit report that is presented to the CHAP Board of Review (held bimonthly) with recommendations for accreditation, deferring, or withdrawing accreditation. The Board of Review then reviews the findings and makes the final accreditation decision. An appeal process exists for any organization that may disagree with Board findings. There is also a mechanism for more immediate action if the site visitors find serious clinical problems that they feel may jeopardize patients.

**Figure 2. CHAP Standards of Excellence; Key "Underlying Principles."**

I. The organization's structure and function consistently support its consumer-oriented philosophy, mission, and purpose.

II. The organization consistently provides high-quality services and products.

III. The organization has adequate human, financial, and physical resources to accomplish its stated mission and purpose.

IV. The organization is positioned for long-term viability.

(CHAP, 2001a).

## CHAP MISSION STATEMENT

CHAP's mission is to provide leadership in enhancing the health and well being of diverse communities. This mission is achieved by:

- developing standards of excellence that assure the management of ethical, humane, and competent care in home, community, and public health settings;
- developing and disseminating innovative products, services, and models of care;
- creating partnerships; and
- utilizing resources efficiently.

(www.chapinc.org/mission.htm)

## Summary

The CHAP accreditation process was established to provide an objective, external process for evaluating an organization's effectiveness in meeting its own mission, while the organization was providing services that meet national care standards. The entire CHAP review process is based on a nursing model of care—that of organizational assessment, strength and weakness identification, appropriate organizational interventions, and evaluation that provides a holistic approach to an organization's performance. CHAP expects to see a home care or hospice organization providing effective services that are appropriate for the patient population and communities it serves.

For more information about the CHAP accreditation process:

**Web site:** www.chapinc.org

**Telephone:** (800) 656-3656, ext. 242

**Mail:** CHAP, 61 Broadway, 33rd Floor, New York, NY 10006

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# Show *Home Healthcare Nurse* **your creative side!**

Have an interesting story about a patient situation you've experienced as a home care nurse? Perhaps you have written a moving poem or thought about how something that happened in your practice would make a humorous cartoon. *Home Healthcare Nurse* would like to share your thoughts and feelings with other readers through poems, cartoons, word puzzles, and serious and amusing anecdotes. We have an illustrator, so don't worry about your artistic abilities. Just send in your ideas and we'll work with you from there. Please make sure that patient confidentiality is assured when writing. We're sure you have something great to share!

**Send your contributions to:**

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**e-mail: chump@homehealth.win.net**

# *AGENDA ITEM J*

# Licensing Committee

| | |
|---|---|
| **Goal 2:** | **Ensure the professional qualifications of licensees.** |
| **Outcome:** | **Qualified licensees** |

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| **Objective 2.1:** | **Issue licenses within three days of a completed application by June 30, 2005.** |
| **Measures:** | **Percentage of licenses issued within 3 days** |
| **Tasks:** | 1. Review 100 percent of all applications within 7 days of receipt.<br>2. Process 100 percent of all deficiency documents within 3 days of receipt.<br>3. Make a licensing decision within 3 days after all deficiencies are corrected.<br>4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.<br>• Pharmacists<br>• Intern pharmacists<br>• Pharmacy technicians<br>• Foreign educated pharmacists (evaluations)<br>• Pharmacies<br>• Non-resident pharmacies<br>• Wholesaler drug facilities<br>• Veterinary food animal drug retailers<br>• Exemptees (the non-pharmacists who may operate sites other than pharmacies)<br>• Out-of-state distributors<br>• Clinics<br>• Hypodermic needle and syringe distributors<br>5. Deny licenses to applicants not meeting board requirements. |

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| **Objective 2.2:**<br><br>**Measure:** | **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**<br><br>**Number of implemented changes** |
| **Tasks:** | 1. Review Pharmacist Intern Program.<br>2. Implement changes to the Pharmacy Technician Program.<br>  a. Use PTCB as a qualifying method for registration.<br>  b. Eliminate clerk-typist from pharmacist supervisory ratio.<br>  c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.<br>2. Administer a pharmacist licensure exam more than twice a year.<br>3. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.<br>4. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.<br>5. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.<br>6. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.<br>7. Issue temporary permits whenever change of ownership occurs.<br>8. Establish means for licensee to renew permits on line. |

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| **Objective 2.3:**<br><br>**Measure:** | **Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.**<br><br>**Number of public policy initiatives evaluated** |
| **Tasks:** | 1. Explore the need to regulate pharmacy benefit managers.<br>2. Explore the need to regulate drugs labeled for "veterinary use only."<br>3. Explore the importation of drugs from foreign countries.<br>4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies. |

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| **Objective 2.4:**<br><br>**Measure:** | **Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.**<br><br>**Percentage of cashiered application and renewal fees within 2 working days** |
| **Tasks:** | 1. Cashier application fees.<br>2. Cashier renewal fees. |

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| **Objective 2.5:**<br><br>**Measure:** | **Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.**<br><br>**Percentage response for verifying licensing information within 5 working days** |
| **Tasks:** | 1. Respond to requests for licensing verification |

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| **Objective 2.6:**<br><br>**Measure:** | **Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**<br><br>**Percentage of licensing records changes within 5 working days** |
| **Tasks:** | 1. Make address and name changes.<br>2. Process discontinuance of businesses forms and related components.<br>3. Process changes in pharmacist-in-charge and exemptee-in-charge.<br>4. Process off-site storage applications. |