State of California | Department of Consumer Affairs

Memorandum

To: **Members, Board of Pharmacy** | Date: January 10, 2005

From: **Virginia Herold**

Subject: **Regulation Report and Action**

1. **Regulations Approved**

Protocol for Furnishing Emergency Contraception: Adopt California Code of Regulations, title 16, section 1746.

This regulation adopts the board's protocol for the dispensing of emergency contraception by pharmacists. The Office of Administrative Law approved this rulemaking in late October, and the regulation takes effect December 2, 2004. Information about this regulation is on the board's Web site and will be discussed in the board's forthcoming newsletter, *The Script.* A copy of the language adopted is provided in Attachment 1.

2. **Pending Regulations -- Awaiting Notice and Board Action**

Proposed amendments to California Code of Regulations, Title 16 – Repeal of Section 1717(3) and to Adopt Section 1713 – Authority to Use Drop Boxes for Prescriptions and Automated Dispensing Devices to Pick-Up Refill Medications

At the October Board Meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devices to dispense refill medication when the patient has "opted–in" to use this system. At the current time, this regulation has not been noticed.

The language is provided as Attachment 2.

3. **Pending Regulations -- Action to Adopt the Modified Regulations to Title 16, California Code of Regulations**

On November 12, 2004, the board published the required public notice and other documents seeking comments on an omnibus group of more than 15 regulations. These documents are provided in Attachment 3.

Two comments were submitted in response to the proposed rulemaking during the 45-day comment period. Both changes are nonsubstantive, technical modifications to section 1745. The specific comments are provided in Attachment 4.

No public hearing has been requested for this omnibus package of regulation changes. As such, the board may take action on any or all of the regulations listed below during this portion of the board meeting.

Action on each regulation section will need a board motion and second, and a vote to adopt.

Staff has also suggested several amendments to the regulations (to sections 1720.1, 1732.05(b)(7), and deletion of section 1715.5 from this rulemaking). Where such changes are proposed, there is a notation made at the start of the respective section identifying the change.

Any changes adopted by the board that differ from the initially noticed language will be released for a 15-day comment period, as required by the Administrative Procedure Act.

The board will then compile and submit the rulemaking to the director of the Department of Consumer Affairs for review.

a) Adoption of Amendments to section 1706.1 --Abandonment of Application Files

§1706.2. Abandonment of Application Files.

(a) An applicant for a ~~permit~~ license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy ~~manufacturer,~~ wholesaler, ~~supplier,~~ out-of-state distributor, or clinic~~, medical device retailer or warehouse of a medical device retailer~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.

(b) An applicant for a pharmacy technician license ~~registration~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4029, ~~4033, 4034,~~ 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, ~~and~~ 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

b) Adoption of section 1712 – Use of pharmacist Identifiers

§1712. Use of Pharmacist Identifiers.
(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.
(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

Note:
Authority cited: sections 4005, Business and Professions Code. Reference: sections 4005 and 4115, Business and Professions Code.

c) Adoption of Amendments to section 1715 – Self Assessment of a Pharmacy by the Pharmacist in Charge

§1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.
(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new pharmacy permit has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
(c) The components of this assessment shall be on Form 17M-13 ~~17I-29 (Rev 1/01)~~ entitled "Community Pharmacy & Hospital Outpatient Pharmacy ~~and Practice~~ Self-Assessment ~~(Including Hospital Pharmacy That Dispenses Prescriptions)~~" or Form 17M-14 ~~17I-30 (Rev 1/01)~~ entitled "Hospital ~~Inpatient~~ Pharmacy ~~and Practice~~ Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations. ~~regarding: facility condition and security, drug stock, posting of certificates and notices, pharmacist-in-charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances provisions, prescription~~

~~requirements, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, record keeping requirements for all dangerous drugs, record keeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber office use, electronic transmission of prescriptions.~~
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, ~~4133,~~ 4305, 4330, 4332 and 4333, Business and Professions Code.

NOTE: At the request of the board's supervising inspectors, the following repeal of section 1715.5 is being withdrawn from this rulemaking until definitive requirements for pharmacies to submit CURES data as directed by the Department of Justice are board are added to the Health and Safety Code. The section will remain in force.

§1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions.

~~The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:~~
~~(a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.~~
~~(b) The above information shall be provided in the following format:~~
~~(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.~~
~~(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic 1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.~~
~~(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled.~~

~~For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).~~
~~(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.~~
~~(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of $75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.~~

Note:
Authority cited: ~~S~~sections 4005, Business and Professions Code. Reference: ~~S~~sections 11164 and 11165, Health and Safety Code.

d) Adoption of Amendments to section 1717 – Pharmacy Practice

§1717. ~~Pharmaceutical~~ Pharmacy Practice.
(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code s~~S~~ection 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted

prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in ~~S~~section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code ~~S~~section 4005.
(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.
(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.
(g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note:

Authority cited: ~~S~~sections 4005, 4075 and 4114, Business and Professions Code. Reference: ~~S~~sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

e) Adoption of Amendments to section 1719 – Recognized Schools of Pharmacy

Article 3. ~~Licentiates in Pharmacy~~ Pharmacist Candidates

§1719. ~~Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

~~(a) Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~

~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~

~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections ~~851, 4005 and~~ 4200 of the Business and Professions Code.

f) Adoption of Amendments to section 1720 – Application for Pharmacist Examination and Licensure

§1720. Application for Pharmacist Examination and Licensure. ~~Registration.~~

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by ~~Section 1749,~~ subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.

(c) ~~An applicant who fails to pay the fee required by Section 1749, subdivision (f) within one year after being notified of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

~~(d)~~ Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 4200 and 4200.2, Business and Professions Code.

g) Adoption of Amendments to section 1720.1 – Graduates of Foreign Pharmacy Schools

Note: staff suggest two changes to this section.

1. ***Correct the name of the FPGEC to Foreign Pharmacy Graduate Equivalency Committee***
2. ***Restore a requirement formerly in section 1719(c) to require foreign graduates who became FPGEC certified before 1996 to meet the Test of Spoken English requirements currently required of all foreign graduates. The FPGEC did not require a score of 50 on the TSE until 1996.***

§1720.1. Graduates of Foreign Pharmacy Schools.
Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate ~~Examination~~ Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~
~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot~~

~~provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 851 and 4200, Business and Professions Code.

h) Adoption of Amendments to section 1725 – Acceptable Pharmacy Coursework of Examination Candidates with Four Failed Attempts

§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~~ recognized school of pharmacy. ~~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.

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4200.1, Business and Professions Code.

i) Adoption of Amendments to section 1726 – Supervision of Intern Pharmacists

§1726. ~~Preceptor.~~ Supervision of Intern Pharmacists.
(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.~~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~~ pharmacist supervising an intern pharmacist shall ~~supervise the intern's activities to~~ provide the experience necessary ~~to make~~ for the intern pharmacist to become proficient in the practice of pharmacy. ~~provision of pharmaceutical services.~~
~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

j) Adoption of Amendments to repeal section 1727 – Intern Pharmacist

§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.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

k) Adoption of Amendments to section 1728 – Requirements for Examination

§1728. ~~Intern Experience--~~Requirements for Examination. ~~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.~~
(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
(C) Experience in both community pharmacy and institutional pharmacy practice settings.
(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
(4) A signed copy of the examination security acknowledgment.
(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.
(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note:

Authority cited: ~~S~~sections 851, and 4005 ~~and 4114~~, Business and Professions Code. Reference: ~~S~~sections 144, 851, ~~4114~~ and 4200, Business and Professions Code.

l) Adoption of Amendments to section 1732-1732.7 – Continuing Education

Note: a technical amendment is proposed by staff to correct a grammatical problem in section 1732.05(b)(7), which is indicated below in double underscore, and double strikeout.

§1732. Definitions.
As used in this article:
(a) ~~An accreditation~~ "Accreditation agency" means ~~is~~ an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ education for pharmacists. ~~, 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~~ "Hour" means at least 50 minutes of contact time.
(c) "Provider" means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

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

§1732.05. Accreditation Agencies for Continuing Education.
(a) The following organizations are approved ~~by the Board~~ as ~~continuing education and~~ accreditation agencies:
(1) The Accreditation Council for Pharmacy Education. ~~American Council on Pharmaceutical Education~~
(2) The Pharmacy Foundation of California. ~~Accreditation Evaluation Service of the California Pharmacists Association~~
(b) ~~Upon written application to the Board, any other organization will be approved by the board if:~~ Accreditation agencies shall:
(1) ~~the organization submits a plan demonstrating that it has the capacity to evaluate~~ Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division. ~~following criteria:~~

~~(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.~~
~~(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.~~
~~(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.~~
~~(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.~~
~~(E) When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.~~
~~(F) Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~
~~1. the educational goals and specific learning objectives of the program.~~
~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~
~~3. the speakers and their credentials.~~
~~(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre- and post-testing, pre-testing along with group discussion and critique of answers, patient case-study discussions and problem solving exercises.~~
~~The provider shall also develop a mechanism for each participant to evaluate the continuing education course.~~
~~(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~
~~1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,~~
~~2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,~~
~~3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.~~
~~(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.~~
~~1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.~~
~~2. For home study and other mediated instructional approaches - acceptable documentation of participation includes:~~

~~a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;~~
~~b. in the case of study groups, the successful completion of the program may be attested to by all participants; or~~
~~c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.~~
(2) ~~The organization agrees to perform the following:(A)~~ Maintain a list of the name and address ~~names and addresses~~ of the ~~persons designated as~~ person responsible for the provider's ~~C.E.~~ continuing education program. The accreditation agency shall require that any change in the ~~designated~~ responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the ~~of such~~ change.
~~(B) Notify the Board of~~
(3) Provide the board with the names, addresses and responsible party of each provider, upon request.
~~(C)~~
(4) Respond to complaints from the board ~~Board~~, providers or from ~~California~~ pharmacists concerning activities of any of its ~~approved~~ accredited providers or their coursework.
~~(D)~~
(5) Review at least ~~a ten percent (10%) sample of coursework, as determined by the Board, but not less than~~ one course per year offered by each provider ~~approved~~ accredited by the agency for compliance with the agency's requirements and requirements of the board ~~Board~~ and, on request, report the findings of such reviews to the board ~~Board~~.
~~(E)~~
(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board~~Board~~; and
~~(F)~~
(7) Verify the ~~attendance of licentiates~~ completion ~~at~~ of a specific continuing education course by an individual pharmacist ~~presentations~~ upon request of the board ~~**this article**~~.~~the Board~~.
(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)~~(1) or to perform in accordance with the terms of its agreement as described in (b)(2)~~ shall constitute cause for revocation of its approval as an accreditation agency by the board ~~Board~~.

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

§1732.1. Requirements for ~~Recognized~~ Accredited Providers.

(a) ~~Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses.~~ No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.

(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.

~~Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.~~

~~(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice. All continuing education coursework shall be:~~

~~(1) accurate and timely;~~

~~(2) presented in an orderly fashion conducive to the learning process;~~

~~(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;~~

~~(4) specifically applicable and pertinent to the practice of pharmacy; and~~

~~(5) based on stated educational goals and objectives.~~

~~(d) All providers~~

(c) Providers shall furnish ~~certificates of completion~~ statements of credit to all participants that complete a continuing education course. ~~enrollees~~. The ~~certificate~~ statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

~~(e)~~

(d) Each ~~recognized~~ provider shall notify the accreditation agency~~, on forms approved by the board, within~~ at least 15 days in advance of the first time each new ~~C.E.~~ continuing education course is offered or presented.

~~(f) All providers~~

(e) Providers shall maintain records of ~~attendance at or~~ completion of their continuing education courses ~~programs~~ for four ~~(4)~~ years.

(f) Providers shall include the following information in promotional materials regarding continuing education courses:

(1) Provider's name.

(2) The number of hours awarded for completion of the course

(3) The course's date of expiration

(4) The provider number assigned by the accreditation agency.

(5) The name of the provider's accrediting agency.

(6) The learning objectives of the program.

(7) The nature of the targeted audiences that may best benefit from participation in the program.
(8) The speakers and their credentials.
(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

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

§1732.2. ~~Coursework from Non-Recognized Providers.~~ Board Accredited Continuing Education.
(a) ~~Non-recognized providers or pharmacists~~ Individuals may petition the ~~Board~~ board to allow continuing education credit for specific coursework which is not offered by a ~~recognized~~ provider but meets the standards of Section 1732.3. ~~relevance to pharmacy practice and educational quality, as set forth in subdivision (c) of section 1732.1.~~
(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

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

§1732.3. ~~Coursework Approval for Providers.~~ Requirements for Continuing Education Courses
(a) Unless denied by the accreditation agency upon audit, all coursework offered by ~~California recognized~~ providers ~~is considered as approved in California.~~ may be used to satisfy the continuing education required by section 1732.5 of this Division.
(b) On a random basis ~~established by the Board~~ or in response to ~~complaints about~~ a ~~particular provider or~~ requests by the board ~~Board~~, the accreditation agency shall review selected coursework. ~~Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course.~~ The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. ~~those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(c).~~
(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.
~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.~~
(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.
(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.
(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.
(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.
(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:
(A) The scientific knowledge or technical skills required for the practice of pharmacy.
(B) Direct and/or indirect patient care.
(C) The management and operation of a pharmacy practice.
(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Note:
Authority cited: ~~S~~sections 4005~~, 4206 and 4232~~, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.
Upon written request from the accreditation agency, relating to an audit of continuing education course ~~coursework~~, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

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

§1732.5. Renewal Requirements for Pharmacist.
(a) Except as provided in ~~S~~section 4234 of the Business and Professions Code and ~~S~~section 1732.6 of this ~~Article~~ Division, each applicant for renewal of a pharmacist license shall submit ~~with the application for renewal~~ proof satisfactory to the board ~~Board that~~, that the applicant has completed 30 hours of continuing education in the prior 24 months. ~~subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.~~
(b) All pharmacists shall retain their certificates of completion for four ~~(4)~~ years following completion of a continuing education course. ~~the program.~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for ~~licensure~~ renewal on the grounds of emergency or hardship by applying to the board ~~Board~~ in writing~~, on a form provided for that purpose,~~ setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board. ~~full Board of Pharmacy~~.

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

m) Adoption of Amendments to section 1745 – Partial Filling of Schedule II Prescriptions

Note: 1. the double underscoring in subdivision (c) represents a change suggested by a commenter.
4. the double underscoring in subdivision (c)(2) represents a change suggested by a commenter.

§1745. Partial Filling of Schedule II Prescriptions.
(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code ~~S~~section 11055) may be partially filled, as defined in paragraph (b), if:
(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code ~~S~~section 1250; or
(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.
(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.
(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within ~~fourteen~~ 60 days following the date of issue;
(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original ~~triplicate~~ prescription, also recording the initials of the pharmacist dispensing the prescription;
(3) No portion of the prescription is dispensed more than 60 ~~30~~ days from the date of issuance of the prescription; and
~~(4) The original triplicate prescription is forwarded to the Department of Justice in conformity with Health and Safety Code section 11164(a) at the end of the month in which the prescription has been completely filled or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first.~~
(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4301, Business and Professions Code; and ~~S~~sections 11055, 11153, 11154, ~~11164,~~ 11166, 11200, Health and Safety Code.

n) Adoption of Amendments to section 1749 – Fee Schedule

§1749. Fee Schedule.
The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with ~~S~~section 4400 of the Business and Professions Code are hereby fixed as follows:
(a) The fee for the issuance of a ~~permit to conduct a~~ pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of ~~said permit~~ pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
(b) The fee for the issuance of a temporary license ~~permit~~ is one hundred seventy-five dollars ($175).
(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25).
(d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).
(e) The fee for regrading an examination is seventy-five dollars ($75).
(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars ($115).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars ($115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents ($57.50).
(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars ($90). The penalty for failure to renew is forty-five dollars ($45).
(j) The fees for a certificate of exemption under the provisions of sections 4053~~,~~ or 4054 ~~and 4133~~ of the Business and Professions Code are as follows:
(1) For the application and investigation of the applicant, the fee is seventy-five dollars ($75).
(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).
(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for ~~registration as~~ an intern pharmacist license ~~or extension of the registration~~ is sixty-five dollars ($65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars ($10).
(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars ($30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars ($60).
(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars ($100). The penalty for failure to renew is fifty dollars ($50).~~
~~(o)~~ The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
~~(p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars ($165).~~
~~(q)~~ (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars ($340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
~~(r) The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars ($170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents ($87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents ($43.75).~~

Note:
Authority cited: ~~S~~sections 163.5 and 4005, Business and Professions Code. Reference: ~~S~~sections 163.5, 4005, 4110, 4112(h), 4120, ~~4130,~~ 4196, 4200~~(c)~~, 4400~~(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w)~~, 4401 and 4403, Business and Professions Code.

o) **Adoption of Amendments to repeal section 1750 – Fee Schedule, Health and Safety Code**

§1750. Fee Schedule--Health and Safety Code.
~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).~~

Note:
Authority cited: ~~S~~section 4005, Business and Professions Code; and ~~S~~section 11127, Health and Safety Code. Reference: ~~S~~section 11127, Health and Safety Code.

Article 8. ~~Rules of Professional Conduct~~ Prohibitions and Discipline

Attachment 1

Protocol for Furnishing Emergency Contraception
CCR, Title 16, Section 1746

Board of Pharmacy
Emergency Contraception
Add Section 1746

§1746. Emergency Contraception.

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052 (a)(8)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive

medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60

Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

NOTE:

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

Attachment 2

Proposal to Use Drop Boxes for Prescriptions and Automated Dispensing Devices to Pick-Up Refill Prescriptions

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use a device to dispense refilled prescriptions when the pharmacy is not open provided:

(1) The device is located at the same address or adjoining the licensed premises.
(2) The device has a means to identify the patient and only release that patient's prescriptions.
(3) The device is secure from access by unauthorized individuals.
(4) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(5) The pharmacy is responsible for the prescriptions stored in the device.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the

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[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Attachment 3

Notice, Initial Statement of Reasons and Exact Language for the Board's 2004 Omnibus Rulemaking

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on December 27, 2004.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on December 13, 2004.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 163.5, 851, 4005, 4075, and 4114, Business and Professions Code; section 11127, Health and Safety Code and to implement, interpret or make specific sections 144, 163.5, 851, 4005, 4019, 4021, 4022, 4027, 4029, 4030, 4037, 4038, 4040, 4043, 4050, 4051, 4052, 4070, 4075, 4081, 4101, 4105, 4110, 4112, 4113, 4114, 4115, 4116, 4117, 4119, 4120, 4127.1, 4160, 4180, 4190, 4196, 4200, 4200.1, 4200.2, 4201, 4202, 4203, 4204, 4205, 4231, 4232, 4234, 4301, 4305, 4330, 4332, 4333, 4342, 4400, 4401, 4403, Business and Professions Code; sections, 11055, 11153, 11154, 11166, 11200, and 11165 Health and Safety Code of the Business and Professions Code, , the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 163.5 of the Business and Professions Code specifies that delinquency fees for licenses issued by an agency within the Department of Consumer Affairs shall be fifty percent of the renewal fee.

Section 851 of the Business and Professions Code permits licensing boards within the Department of Consumer Affairs to require applicants to meet the standards of a private voluntary society or association.

Section 4005 of the Business and Professions Code authorizes the board to adopt rules and regulations for the protection of the public including the following:

- For the proper and more effective enforcement and administration of the Pharmacy Law
- Pertaining to the practice of pharmacy
- Pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed
- Providing for standards of minimum equipment for establishments licensed under this chapter

Section 4019 of the Business and Professions Code defines "order."

Section 4021 of the Business and Professions Code defines "controlled substance."

Section 4022 of the Business and Professions Code defines "dangerous drug or dangerous device."

Section 4027 of the Business and Professions Code defines "licensed health care facility."

Section 4029 of the Business and Professions Code defines "hospital pharmacy."

Section 4030 of the Business and Professions Code defines "intern pharmacist."

Section 4037 of the Business and Professions Code defines "pharmacy."

Section 4038 of the Business and Professions Code defines "pharmacy technician."

Section 4040 of the Business and Professions Code defines "prescription."

Section 4043 of the Business and Professions Code defines "wholesaler."

Section 4050 of the Business and Professions Code declares the practice of pharmacy to be a profession.

Section 4051 of the Business and Professions Code prohibits the practice of pharmacy without a license.

Section 4052 of the Business and Professions Code specifies those professional services that a pharmacist may provide.

Section 4070 of the Business and Professions Code establishes requirements for handling electronic prescriptions.

Section 4075 of the Business and Professions Code permits the board to adopt regulations designed to prevent the unauthorized furnishing of drugs.

Section 4081 of the Business and Professions Code establishes record keeping and inventory requirements for board licensees.

Section 4101 of the Business and Professions Code requires notification of the board when a pharmacist-in-charge or exemptee-in-charge terminates employment.

Section 4105 of the Business and Professions Code establishes requirements for board licensees related to the handling and storage of required documentation.

Section 4110 of the Business and Professions Code prohibits the operation of a pharmacy without a license from the Board of Pharmacy.

Section 4112 of the Business and Professions Code requires non-resident pharmacies to register with the Board of Pharmacy.

Section 4113 of the Business and Professions Code requires each pharmacy to designate a pharmacist-in-charge and specifies that the pharmacist-in-charge is responsible for the lawful operation of the pharmacy.

Section 4114 of the Business and Professions Code permits the board to adopt regulations governing the activities of pharmacy interns.

Section 4115 of the Business and Professions Code specifies the activities that may be performed by a pharmacy technician.

Section 4116 of the Business and Professions Code specifies who may enter a pharmacy and grants the board authority to adopt regulations requiring security measures in pharmacies.

Section 4117 of the Business and Professions Code restricts access to a hospital pharmacy to certain personnel.

Section 4119 of the Business and Professions Code permits pharmacies to furnish dangerous drugs or dangerous devices to licensed health facilities emergency medical service providers under specified circumstances.

Section 4120 of the Business and Professions Code requires drug wholesalers to obtain a license from the Board of Pharmacy and makes declarations regarding non-resident pharmacies.

Section 4127.1 of the Business and Professions Code requires pharmacies compounding sterile injectable drug products to be licensed by the Board of Pharmacy.

Section 4160 of the Business and Professions Code requires drug wholesalers to be licensed by the Board of Pharmacy.

Section 4161 of the Business and Professions Code requires out-of-state distributors to be licensed by the Board of Pharmacy.

Section 4180 of the Business and Professions Code permits specified clinics to obtain a license to purchase drugs from the Board of Pharmacy.

Section 4190 of the Business and Professions Code permits surgical clinics to obtain a license to purchase drugs from the Board of Pharmacy.

Section 4196 of the Business and Professions Code requires veterinary food-animal drug retailers to be licensed by the board.

Section 4200 of the Business and Professions Code specifies the requirements to become licensed as a pharmacist.

Section 4200.1 of the Business and Professions Code requires that pharmacist candidates who fail the licensure examination four times must satisfy additional education requirements.

Section 4200.2 of the Business and Professions Code specifies the content of the Multi-State Pharmacy Jurisprudence Examination.

Section 4201 of the Business and Professions Code specifies the information required of an applicant for a site license from the Board of Pharmacy.

Section 4202 of the Business and Professions Code specifies the requirements to become licensed as a pharmacy technician.

Section 4203 of the Business and Professions Code specifies the requirements of an application for a clinic license issued pursuant to Section 4180.

Section 4204 of the Business and Professions Code specifies the requirements of an application for a clinic license issued pursuant to Section 4190.

Section 4205 of the Business and Professions Code specifies the requirements for a hypodermic license issued pursuant to Section 4141.

Section 4231 of the Business and Professions Code requires pharmacists to complete continuing education as a condition of renewing their license.

Section 4232 of the Business and Professions Code specifies the content of continuing education courses.

Section 4234 of the Business and Professions Code permits the Board of Pharmacy to make exceptions to the continuing education requirement in emergency or hardship cases.

Section 4301 of the Business and Professions Code requires the Board of Pharmacy to take action against any licensee who is guilty of unprofessional conduct and defines unprofessional conduct.

Section 4305 of the Business and Professions Code specifies that the failure to notify the Board of Pharmacy of the termination of the pharmacist-in-charge of a pharmacy is grounds for disciplinary action.

Section 4330 of the Business and Professions Code specifies that failing to put a pharmacist in charge of a pharmacy or interference with the pharmacist-in-charge operating the pharmacy in a lawful manner is a misdemeanor.

Section 4332 of the Business and Professions Code specifies that violation of the record keeping requirements of Section 4081 is a misdemeanor.

Section 4333 of the Business and Professions Code requires that records required by section 4081 must be kept on the premises for three years and further specifies that violation of that requirement is a misdemeanor.

Section 4342 of the Business and Professions Code permits the Board of Pharmacy to take actions to prevent the distribution of unsafe drugs and devices.

Section 4400 of the Business and Professions Code specifies the fees for various licenses issued by the Board of Pharmacy.

Section 4401 of the Business and Professions Code requires pharmacists to renew their licenses every two years.

Section 4403 of the Business and Professions Code prohibits the board from issuing or renewing a pharmacist license without the required fees.

Section 11055 of the Health and Safety Code specifies those chemical entities classified as Schedule II controlled substances.

Section 11153 of the Health and Safety Code specifies that a pharmacist has a responsibility to ensure that a controlled substance is issued for a legitimate medical purpose.

Section 11154 of the Health and Safety Code prohibits the dispensing or furnishing of a controlled substance in violation of the California Uniform Controlled Substances Act.

Section 11166 of the Health and Safety Code prohibits the dispensing of a controlled substance prescription after six months from the date of issuance.

Section 11200 of the Health and Safety Code specifies the circumstances under which a controlled substance prescription may be dispensed or refilled.

Section 11165 of the Health and Safety Code generally establishes the Controlled Substance Utilization and Review Evaluation System and requires pharmacies to periodically report the dispensing of Schedule II and Schedule III prescriptions to the Department of Justice.

1. Section 1706.2

This change consolidates provisions related to the abandonment of applications.

2. Section 1712

Senate Bill 1913 (Chapter 695, Statutes of 2004) amended Business and Professions Code section 4115 to allow the use of systems approved by board regulations and this regulation implements that provision.

3. Section 1715

Existing versions of the pharmacy self assessment forms require updating to reflect numerous recent changes to pharmacy law.

4. Section 1715.5

This section is repealed because Senate Bill 151 (Chapter 406, Statutes of 2003) amended section 11165 of the Health and Safety Code to specify how pharmacies must report the dispensing of controlled substances.

5. Section 1717

This section is amended to make technical corrections.

6. Section 1719

This change will allow the board to issue intern pharmacist licenses to students in pharmacy schools with candidate status and for the board to allow graduates of pharmacy schools with candidate status to sit for the licensing examinations. Schools with candidate status are at the penultimate step of accreditation, but final accreditation can occur after students have been enrolled and need to obtain internship hours or to be qualified to take the licensure examinations.

7. Section 1720

These changes are made to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2003) and to delete provisions related to application abandonment that are relocated to section 1706.2.

8. Section 1720.1

Senate Bill 1913 (Chapter 695, Statutes of 2004) requires graduates of foreign pharmacy schools to become certified by the FPGEC. FPGEC has the same degree and education requirements specified in section 4200 which makes board evaluation of those standards redundant.

9. Section 1725

These are technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

10. Section 1726

Interns are no longer required to be supervised by preceptors. Accordingly, references to preceptors are eliminated.

11. Section 1727

Senate Bill 1913 (Chapter 695, Statutes of 2004) establishes the standards for issuing intern pharmacist licenses in Section 4208 of the Business and Professions Code and are inconsistent with existing provisions of this section.

12. Section 1728

The proposed regulation will streamline the board's application process by requiring pharmacist candidates to have completed all other requirements for licensure prior to applying to take the

licensure examinations. The intern hour requirements have been amended to eliminate the first year maximum and preceptor supervision requirements to reflect changes to the pharmacy curriculum in ACPE accredited pharmacy schools.

13. Section 1732

The proposed regulation would eliminate unnecessary definitions.

14. Section 1732.05

The changes update and clarify existing requirements for continuing education accreditation agencies.

15. Section 1732.1

The changes update and clarify existing requirements for continuing education providers.

16. Section 1732.2

The changes update and clarify existing requirements for Board of Pharmacy accredited continuing education providers.

17. Section 1732.3

The changes update and clarify existing requirements for continuing education courses.

18. Section 1732.4

The proposed changes make minor technical changes.

19. Section 1732.5

The proposed changes make minor technical changes.

20. Section 1732.6

The proposed changes make minor technical changes.

21. Section 1732.7

The proposed changes make minor technical changes.

22. Section 1745

Changes made by Senate Bill 151 (Chapter 406, Statutes of 2003) allow the period for partial filling to be extended to 60 days and expands the authority to perform partial fills when a pharmacy does not have an adequate supply to fill the entire prescription in conformance with 21CFR section 1306.13. These changes will provide patients and pharmacists with greater flexibility when

handling Schedule II prescriptions.

23. Section 1749

The proposed regulation includes minor technical changes and the following substantive changes:

1. Subdivision (l) eliminates language relating to the extension of an intern pharmacist license in conformance with Business and Professions Code section 4208 which prohibits the extension or renewal of an intern pharmacist license.
2. Subdivision (m) is eliminated because this fee is specified in statute (Business and Professions Code section 4400) and existing language duplicates that provision.
3. Subdivision (n) is eliminated to conform with changes to continuing education regulations proposed in this rulemaking.
4. Subdivision (p) is eliminated to conform with changes regarding foreign graduates proposed in this rulemaking.
5. Subdivision (r) is eliminated because the board no longer regulates medical device retailers.

24. Section 1750

This section is repealed to conform with the repeal of its authorizing statute (section 11127 of the Health and Safety Code).

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the

elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The proposed regulations provide greater flexibility to pharmacies and streamline application processes for certain license classifications.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070
	Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4005
Fax No.:	(916) 327-6308
E-Mail Address:	Virginia_Herold@dca.ca.gov

The backup contact person is:

Name:	Patricia Harris
Address:	400 R Street, Suite 4070
	Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4004
Fax No.:	(916) 327-6308
E-Mail Address:	Patricia_Harris@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Pharmacist Identification, Pharmacy Self Assessment, Pharmacist Candidates, Continuing Education, Fees, Partial Filling of Schedule II prescriptions

Title 16 Sections Affected: 1706.2, 1712, 1715, 1715.5, 1717, 1719, 1720, 1720.1, 1725, 1726, 1727, 1728, 1732, 1732.05, 1732.1, 1732.2, 1732.3, 1732.4, 1732.5, 1732.6, 1732.7, 1745, 1749, 1750

Specific Purpose of the Proposed Changes:

Proposed amendments to section 1706.2 relocates provisions from section 1720 related to the abandonment of applications.

Proposed amendments to section 1712 specifies the requirements of electronic systems used in pharmacies to record the identity of the reviewing pharmacist.

Proposed amendments to section 1715 replace the existing self-assessment forms for community and hospital pharmacies with new forms reflecting recent changes to pharmacy law.

Proposed amendment to section 1715.5 is repealed.

Proposed amendments to section 1717 is amended to make technical corrections and to relocate the provisions of subdivision (e) to section 1712.

Proposed amendments to section 1719 is amended to delete the existing provisions and to recognize schools of pharmacy that are granted candidate status or full accreditation by the Accreditation Council for Pharmacy Education (ACPE).

Proposed amendments to section 1720 is amended to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2004) and to delete provisions related to application abandonment that are relocated to section 1706.2.

Proposed amendments to section 1720.1 deletes the existing provisions and deems graduates of foreign pharmacy schools who are certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) to have satisfied the degree and education requirements for licensure as a pharmacist.

Proposed amendments to section 1725 makes technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

Proposed amendments to section 1726 deletes provisions relating to pharmacy preceptors.

Proposed repeal of section 1727 delete the existing provisions.

Proposed amendments to section 1728 deletes the existing provisions and establishes the requirements for pharmacist candidates to sit for the licensure examinations.

Proposed amendments to section 1732 revises and updates definitions related to continuing education.

Proposed amendments to section 1732.05 reorganizes and recasts existing provisions relating to continuing education accreditation agencies.

Proposed amendments to section 1732.1 reorganizes and recasts existing provisions relating to continuing education providers.

Proposed amendments to section 1732.2 reorganizes and recasts existing provisions relating to continuing education providers accredited by the Board of Pharmacy.

Proposed amendments to section 1732.3 reorganizes and recasts existing provisions relating to continuing education courses.

Proposed amendments to section 1732.4 makes minor technical changes.

Proposed amendments to section 1732.5 makes minor technical changes.

Proposed amendments to section 1732.6 makes minor technical changes.

Proposed amendments to section 1732.7 makes minor technical changes.

Proposed amendments to section 1745 revises existing provisions relating to the partial filling of Schedule II controlled substance prescriptions.

Proposed amendments to section 1749 makes minor technical changes and eliminates fees that are no longer necessary. The fees for a foreign pharmacy graduate application and providers of education are eliminated to conform with changes proposed in this rulemaking.

Proposed repeal of section 1750 because the board can no longer issue such a license.

Factual Basis/Rationale

Section 1706.2

This change consolidates provisions related to the abandonment of applications.

Section 1712

Senate Bill 1913 (Chapter 695, Statutes of 2004) amended Business and Professions Code section 4115 to allow the use of systems approved by board regulations and this regulation implements that provision.

Section 1715

Existing versions of the pharmacy self assessment forms require updating to reflect numerous recent changes to pharmacy law.

Section 1715.5

This section is repealed because Senate Bill 151 (Chapter 406, Statutes of 2003) amended section 11165 of the Health and Safety Code to specify how pharmacies must report the dispensing of controlled substances.

Section 1717

This section is amended to make technical corrections and to relocate the provisions of subdivision (e) to section 1712.

Section 1719

This change will allow the board to issue intern pharmacist licenses to students in pharmacy schools with candidate status and for the board to allow graduates of pharmacy schools with candidate status to sit for the licensing examinations. Schools with candidate status are at the penultimate step of accreditation, but final accreditation can occur after students have been enrolled and need to obtain internship hours or to be qualified to take the licensure examinations.

Section 1720

These changes are made to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2004) and to delete provisions related to application abandonment that are relocated to section 1706.2.

Section 1720.1

Senate Bill 1913 (Chapter 695, Statutes of 2004) requires graduates of foreign pharmacy schools to become certified by the FPGEC. FPGEC has the same degree and education requirements specified in section 4200 which makes board evaluation of those standards redundant.

Section 1725

These are technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

Section 1726

Interns are no longer required to be supervised by preceptors. Accordingly, references to preceptors are eliminated.

Section 1727

Senate Bill 1913 (Chapter 695, Statutes of 2004) establishes the standards for issuing intern pharmacist licenses in section 4208 of the Business and Professions Code and are inconsistent with existing provisions of this section.

Section 1728

The proposed regulation will streamline the board's application process by requiring pharmacist candidates to have completed all other requirements for licensure prior to applying to take the licensure examinations. The intern hour requirements have been amended to eliminate the first year

maximum and preceptor supervision requirements to reflect changes to the pharmacy curriculum in ACPE accredited pharmacy schools.

Section 1732

The proposed regulation would eliminate unnecessary definitions.

Section 1732.05

The changes update and clarify existing requirements for continuing education accreditation agencies.

Section 1732.1

The changes update and clarify existing requirements for continuing education providers.

Section 1732.2

The changes update and clarify existing requirements for Board of Pharmacy accredited continuing education providers.

Section 1732.3

The changes update and clarify existing requirements for continuing education courses.

Section 1732.4

The proposed changes make minor technical changes.

Section 1732.5

The proposed changes make minor technical changes.

Section 1732.6

The proposed changes make minor technical changes.

Section 1732.7

The proposed changes make minor technical changes.

Section 1745

Changes made by Senate Bill 151 (Chapter 406, Statutes of 2003) allow the period for partial filling to be extended to 60 days and expands the authority to perform partial fills when a pharmacy does not have an adequate supply to fill the entire prescription in conformance with 21CFR section 1306.13. These changes will provide patients and pharmacists with greater flexibility when handling Schedule II prescriptions.

Section 1749

The proposed regulation includes minor technical changes and the following substantive changes:

1. Subdivision (l) eliminates language relating to the extension of an intern pharmacist license in conformance with Business and Professions Code section 4208 which prohibits the extension or renewal of an intern pharmacist license.
2. Subdivision (m) is eliminated because this fee is specified in statute (Business and Professions Code section 4400) and existing language duplicates that provision.
3. Subdivision (n) is eliminated to conform with changes to continuing education regulations proposed in this rulemaking.
4. Subdivision (p) is eliminated to conform with changes regarding foreign graduates proposed in this rulemaking.
5. Subdivision (r) is eliminated because the board no longer regulates medical device retailers.

Section 1750

This section is repealed to conform with the repeal of its authorizing statute (section 11127 of the Health and Safety Code).

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Board of Pharmacy
Title 16
Proposed Changes

§1706.2. Abandonment of Application Files.

(a) An applicant for a ~~permit~~ license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy ~~manufacturer,~~ wholesaler, ~~supplier,~~ out-of-state distributor, or clinic~~, medical device retailer or warehouse of a medical device retailer~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license ~~registration~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4029, ~~4033, 4034,~~ 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, ~~and~~ 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

§1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.
(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

Note:

Authority cited: sections 4005, Business and Professions Code. Reference: sections 4005 and 4115, Business and Professions Code.

§1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July

1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(c) The components of this assessment shall be on Form 17M-13 ~~17I-29 (Rev 1/01)~~ entitled "Community Pharmacy & Hospital Outpatient Pharmacy ~~and Practice~~ Self-Assessment ~~(Including Hospital Pharmacy That Dispenses Prescriptions)~~" or Form 17M-14 ~~17I-30 (Rev 1/01)~~ entitled "Hospital ~~Inpatient~~ Pharmacy ~~and Practice~~ Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations. ~~regarding: facility condition and security, drug stock, posting of certificates and notices, pharmacist-in-charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances provisions, prescription requirements, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, record keeping requirements for all dangerous drugs, record keeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber office use, electronic transmission of prescriptions.~~
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, ~~4133,~~ 4305, 4330, 4332 and 4333, Business and Professions Code.

§1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions.

~~The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:~~
~~(a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.~~
~~(b) The above information shall be provided in the following format:~~

~~(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.~~

~~(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic 1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.~~

~~(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled.~~

~~For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).~~

~~(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.~~

~~(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of $75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.~~

Note:

Authority cited: ~~S~~sections 4005, Business and Professions Code. Reference: ~~S~~sections 11164 and 11165, Health and Safety Code.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code s~~S~~ection 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

Chart orders as defined in ~~S~~section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code ~~S~~section 4005.

(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.
(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

(g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note:

Authority cited: ~~S~~sections 4005, 4075 and 4114, Business and Professions Code. Reference: ~~S~~sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Article 3. ~~Licentiates in Pharmacy~~ Pharmacist Candidates

§1719. ~~Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

~~(a) Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~
~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~
~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections ~~851, 4005 and~~ 4200 of the Business and Professions Code.

§1720. Application for Pharmacist Examination and Licensure. ~~Registration.~~

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.
(b) The fee required by ~~Section 1749,~~ subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.
(c) ~~An applicant who fails to pay the fee required by Section 1749, subdivision (f) within one year after being notified of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~
~~(d)~~ Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 4200 and 4200.2, Business and Professions Code.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Examination Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a).
~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign~~

~~Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~
~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 851 and 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~~ recognized school of pharmacy. ~~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.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4200.1, Business and Professions Code.

§1726. ~~Preceptor.~~ Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.~~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~~ pharmacist supervising an intern pharmacist shall ~~supervise the intern's activities to~~ provide the experience necessary ~~to make~~ for the intern pharmacist to become proficient in the practice of pharmacy. ~~provision of pharmaceutical services.~~
~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Note:

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

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

§1728. ~~Intern Experience~~--Requirements for Examination. ~~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.~~

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

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

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

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

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

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

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

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

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

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

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

Note:

Authority cited: ~~S~~sections 851, and 4005 ~~and 4114~~, Business and Professions Code. Reference: ~~S~~sections 144, 851, ~~4114~~ and 4200, Business and Professions Code.

§1732. Definitions.

As used in this article:

(a) ~~An accreditation~~ "Accreditation agency" means ~~is~~ an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ education for pharmacists. ~~, 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~~ "Hour" means at least 50 minutes of contact time.

(c) "Provider" means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

Note:

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

§1732.05. Accreditation Agencies for Continuing Education.

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

(1) The Accreditation Council for Pharmacy Education. ~~American Council on Pharmaceutical Education~~

(2) The Pharmacy Foundation of California. ~~Accreditation Evaluation Service of the California Pharmacists Association~~

(b) ~~Upon written application to the Board, any other organization will be approved by the board if:~~ Accreditation agencies shall:

(1) ~~the organization submits a plan demonstrating that it has the capacity to evaluate~~ Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

~~following criteria:~~

~~(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.~~

~~(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.~~

~~(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.~~

~~(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.~~

~~(E) When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.~~

~~(F) Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~

~~1. the educational goals and specific learning objectives of the program.~~

~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~

~~3. the speakers and their credentials.~~

~~(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre- and post-testing, pre-testing along with group discussion and critique of answers, patient case-study discussions and problem solving exercises.~~

~~The provider shall also develop a mechanism for each participant to evaluate the continuing education course.~~

~~(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to~~

~~determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~

~~1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,~~

~~2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,~~

~~3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.~~

~~(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.~~

~~1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.~~

~~2. For home study and other mediated instructional approaches--acceptable documentation of participation includes:~~

~~a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;~~

~~b. in the case of study groups, the successful completion of the program may be attested to by all participants; or~~

~~c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.~~

(2) ~~The organization agrees to perform the following:(A)~~ Maintain a list of the name and address ~~names and addresses~~ of the ~~persons designated as~~ person responsible for the provider's ~~C.E.~~ continuing education program. The accreditation agency shall require that any change in the ~~designated~~ responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the ~~of such~~ change.

~~(B) Notify the Board of~~

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

~~(C)~~

(4) Respond to complaints from the board ~~Board~~, providers or from ~~California~~ pharmacists concerning activities of any of its ~~approved~~ accredited providers or their coursework.

~~(D)~~

(5) Review at least ~~a ten percent (10%) sample of coursework, as determined by the Board, but not less than~~ one course per year offered by each provider ~~approved~~ accredited by the agency for compliance with the agency's requirements and requirements of the board ~~Board~~ and, on request, report the findings of such reviews to the board ~~Board~~.

~~(E)~~

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board~~Board~~; and

~~(F)~~

(7) Verify the ~~attendance of licentiates~~ completion ~~at~~ of a specific continuing education course by an individual pharmacist ~~presentations~~ upon request of this article.~~the Board~~.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)~~(1) or to perform in accordance with the terms of its agreement as described in (b)(2)~~ shall constitute cause for revocation of its approval as an accreditation agency by the board ~~Board~~.

Note:

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

§1732.1. Requirements for ~~Recognized~~ Accredited Providers.

(a) ~~Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses.~~ No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.
(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.
~~Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.~~
~~(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice. All continuing education coursework shall be:~~
~~(1) accurate and timely;~~
~~(2) presented in an orderly fashion conducive to the learning process;~~
~~(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;~~
~~(4) specifically applicable and pertinent to the practice of pharmacy; and~~
~~(5) based on stated educational goals and objectives.~~
~~(d) All providers~~
(c) Providers shall furnish ~~certificates of completion~~ statements of credit to all participants that complete a continuing education course. ~~enrollees~~. The ~~certificate~~ statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.
~~(e)~~
(d) Each ~~recognized~~ provider shall notify the accreditation agency~~, on forms approved by the board, within~~ at least 15 days in advance of the first time each new ~~C.E.~~ continuing education course is offered or presented.
~~(f) All providers~~
(e) Providers shall maintain records of ~~attendance at or~~ completion of their continuing education courses ~~programs~~ for four ~~(4)~~ years.
(f) Providers shall include the following information in promotional materials regarding continuing education courses:
(1) Provider's name.
(2) The number of hours awarded for completion of the course
(3) The course's date of expiration

(4) The provider number assigned by the accreditation agency.
(5) The name of the provider's accrediting agency.
(6) The learning objectives of the program.
(7) The nature of the targeted audiences that may best benefit from participation in the program.
(8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

Note:

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

§1732.2. ~~Coursework from Non-Recognized Providers.~~ Board Accredited Continuing Education.

(a) ~~Non-recognized providers or pharmacists~~ Individuals may petition the ~~Board~~ board to allow continuing education credit for specific coursework which is not offered by a ~~recognized~~ provider but meets the standards of Section 1732.3. ~~relevance to pharmacy practice and educational quality, as set forth in subdivision (c) of section 1732.1.~~
(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

Note:

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

§1732.3. ~~Coursework Approval for Providers.~~ Requirements for Continuing Education Courses

(a) Unless denied by the accreditation agency upon audit, all coursework offered by ~~California recognized~~ providers ~~is considered as approved in California.~~ may be used to satisfy the continuing education required by section 1732.5 of this Division.
(b) On a random basis ~~established by the Board~~ or in response to ~~complaints about~~ a ~~particular provider or~~ requests by the board ~~Board~~, the accreditation agency shall review selected coursework. ~~Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course.~~ The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. ~~those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(c).~~
(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.
~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.~~

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Note:

Authority cited: ~~S~~sections 4005~~, 4206 and 4232~~, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course ~~coursework~~, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

Note:

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

§1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in ~~S~~section 4234 of the Business and Professions Code and ~~S~~section 1732.6 of this ~~Article~~ Division, each applicant for renewal of a pharmacist license shall submit ~~with the application for renewal~~ proof satisfactory to the board ~~Board that~~, that the applicant has completed 30 hours of continuing education in the prior 24 months. ~~subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.~~

(b) All pharmacists shall retain their certificates of completion for four ~~(4)~~ years following completion of a continuing education course. ~~the program.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for ~~licensure~~ renewal on the grounds of emergency or hardship by applying to the board ~~Board~~ in writing~~, on a form provided for that purpose,~~ setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board. ~~full Board of Pharmacy~~.

Note:

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

§1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code ~~S~~section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code ~~S~~section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription, all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within ~~fourteen~~ 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original triplicate prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 ~~30~~ days from the date of issuance of the prescription; and

~~(4) The original triplicate prescription is forwarded to the Department of Justice in conformity with Health and Safety Code section 11164(a) at the end of the month in which the prescription has been completely filled or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first.~~

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4301, Business and Professions Code; and ~~S~~sections 11055, 11153, 11154, ~~11164,~~ 11166, 11200, Health and Safety Code.

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with ~~S~~section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a ~~permit to conduct a~~ pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of ~~said permit~~ pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
(b) The fee for the issuance of a temporary license ~~permit~~ is one hundred seventy-five dollars ($175).
(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25). (d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).
(e) The fee for regrading an examination is seventy-five dollars ($75).
(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars ($115).
(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars ($115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents ($57.50).
(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars ($90). The penalty for failure to renew is forty-five dollars ($45).
(j) The fees for a certificate of exemption under the provisions of sections 4053~~,~~ or 4054 ~~and 4133~~ of the Business and Professions Code are as follows:

(1) For the application and investigation of the applicant, the fee is seventy-five dollars ($75).
(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for ~~registration as~~ an intern pharmacist license ~~or extension of the registration~~ is sixty-five dollars ($65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars ($10).

(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars ($30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars ($60).
(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars ($100). The penalty for failure to renew is fifty dollars ($50).~~
~~(o)~~ The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
~~(p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars ($165).~~
~~(q)~~ (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars ($340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
~~(r) The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars ($170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents ($87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents ($43.75).~~

Note:

Authority cited: ~~S~~sections 163.5 and 4005, Business and Professions Code. Reference: ~~S~~sections 163.5, 4005, 4110, 4112(h), 4120, ~~4130,~~ 4196, 4200~~(c)~~, 4400~~(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w)~~, 4401 and 4403, Business and Professions Code.

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code; and ~~S~~section 11127, Health and Safety Code. Reference: ~~S~~s ection 11127, Health and Safety Code.

Article 8. ~~Rules of Professional Conduct~~ Prohibitions and Discipline

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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www.pharmacy.ca.gov

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

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # ___ _____ or Accredited by:

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

17M-13

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
(Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

17. _____ TCH # _____ Exp. Date: _____

18. _____ TCH # _____ Exp. Date: _____

_____
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All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes	No	N/A	
☐	☐	☐	The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)
☐	☐	☐	The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises, fixtures, and equipment is maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)
☐	☐	☐	If applicable, a notice of shared electronic prescription files is posted in public view where it can be clearly read by the purchasing public. (CCR 1717.2)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	The original board-issued pharmacy license and the current renewal is posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 23 – "Compounding Sterile Injectable Drugs".)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Delivery of Drugs

Yes	No	N/A	
☐	☐	☐	Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a])
☐	☐	☐	A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):
☐	☐	☐	The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
☐	☐	☐	Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
☐	☐	☐	The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
☐	☐	☐	The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
☐	☐	☐	The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Drug Stock

Yes	No	N/A	
☐	☐	☐	The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22CCR 70263[q])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐☐☐ The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the exemptee-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709[c])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Duties of a Pharmacist

Yes No N/A

☐☐☐ The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are per formed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1793.1)

☐☐☐ The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy

related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, CCR 1726, 1727)

☐☐☐ All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐☐☐ Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

9. Consultation/Patient Profile/Review of Drug Therapy

Pharmacists provide oral consultation (CCR 1707.2):

Yes No N/A

☐☐☐ whenever the prescription drug has not been previously dispensed to the patient;

☐☐☐ whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;

☐☐☐ upon request; and

☐☐☐ whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

☐☐☐ The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Prescription Requirements

Yes No N/A

☐☐☐ Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717)

☐☐☐ The security and confidentiality of electronically transmitted prescriptions are maintained. (CCR 1717.4)

☐☐☐ Facsimile prescriptions are received only from prescriber's office. (B&PC 4040[c])

☐☐☐ Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

☐☐☐ All written controlled substances prescriptions (schedule II – V) are on California Security Prescription forms. (H&S 11164[a])

☐☐☐ All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&S 11164[a] [1] and H&S 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076, CCR 1718.1)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution is communicated to the patient. (B&PC 4073)

Yes No N/A

☐☐☐ If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

☐☐☐ Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&S 12000)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

12. Refill Authorization

Yes No N/A

☐☐☐ Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ Refills are documented. (CCR 1717)

☐☐☐ Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ Refills for Schedule II controlled substances are prohibited. (H&S 11200)

☐☐☐ Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (H&S 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR1711[c][2][A], 1711[c][3]

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐☐☐ Date, location, and participants in the quality assurance review;

☐☐☐ Pertinent data and other information related to the medication error(s) reviewed;

☐☐☐ Findings and determinations; and

☐☐☐ Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

Yes No N/A

☐☐☐ Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&S 11153)

☐☐☐ Even after conferring with the prescriber, the pharmacist does not dispenses a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Prescription Transfer

Yes No N/A

☐☐☐ Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[f][1-6])

☐☐☐ Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Prescription Transfers

☐☐☐ For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

☐☐☐ For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[f], CFR 1306.26)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 5556 et seq.)

☐☐☐ All prescriptions are kept confidential and only disclosed as authorized by law. (CCR1764)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

Yes No N/A

☐☐☐ If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4)

☐☐☐ If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR1717.1)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

☐☐☐ Prescription records (CCR 4081[a])

☐☐☐ Purchase Invoices for all prescription drugs (4081[b])

☐☐☐ Biennial controlled substances inventory (21 CFR 1304.11)

☐☐☐ U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)

☐☐☐ Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐☐☐ Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐☐☐ Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)

☐☐☐ Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

Hypodermic needle & syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140 –4149)

☐☐☐ Persons known to the pharmacist and the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

Yes No N/A

☐☐☐ Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐☐☐ The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project.

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

DEA controlled substances inventory:

☐☐☐ Is completed biennially (every two years). Date completed: _____ (21CFR 1304.11[b])

☐☐☐ Schedule II inventory is separate from Schedule 111, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ Is available for inspection for three years. (CCR 1718)

☐☐☐ Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

☐☐☐ Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

☐☐☐ Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21CFR 1304.04)

☐☐☐ U.S. Official Order Form (DEA Form-222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form-222. (21CFR1305.09[e])

☐☐☐ When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form-222 is prepared by the purchasing pharmacy and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.09[e])

☐☐☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form-222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.09[d])

Yes No N/A

☐☐☐ Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year, otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22,1988] 503. B&PC 4160)

☐☐☐ When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ All Schedule II and III controlled substance dispensing data successfully transmitted to CURES by the 18th of each month. (H&SC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ An oral prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form. The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing

pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5

Yes No N/A

☐☐☐ All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR1717.4)

☐☐☐ Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (1717.4[e])

☐☐☐ All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (1717.4[c])

☐☐☐ Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (1717.4[d])

☐☐☐ If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (CFR 1306.13[a])

☐☐☐ The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill". (21 CFR 1306.13[b], CCR 1745)

☐☐☐ The pharmacist, in an a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&S 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Automated Dispensing

Yes No N/A

☐☐☐ The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, H&SC 110105)

For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Health Services, the following is required:

Yes No N/A

☐☐☐ Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])

☐☐☐ A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

☐☐☐ Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

☐☐☐ Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])

☐☐☐ Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430)

☐☐☐ A log is maintained for drugs pre-packed for future dispensing. (CCR 1716.2)

☐☐☐ Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Refill Pharmacy

Yes No N/A

☐☐☐ Pharmacy processes refills for another California licensed pharmacy (1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

Yes No N/A

☐☐☐ Some or all pharmacy refill orders are processed by another California licensed pharmacy. (1707.4[a])

If the answer is "yes" , name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section 22.

☐☐☐ Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (1707.4[a][1])

☐☐☐ Refill prescription label meets requirements of B&PC 4076 and shows the name and address of the refilling and or originating pharmacy. (1707.4[a][2])

☐☐☐ Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (1707.4[a][3])

☐☐☐ Both pharmacies maintain complete and accurate records or refill. (1707.4[a][4])

☐☐☐ Both pharmacies are responsible for accuracy of the refilled prescription. (1707.4[a][5])

☐☐☐ Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Policies and Procedures

There are written policies and procedures in place for:

Yes No N/A

☐☐☐ The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052[a][5][A][iii])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

☐☐☐ Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

Yes No N/A

☐☐☐ Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐☐☐ Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

☐☐☐ The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present. (B&PC 4059.5[f][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

The pharmacy has a designated area or cleanroom for the preparation of sterile products that has the following:

☐☐☐ An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom; (B&PC 4127.7[a])

☐☐☐ A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

☐☐☐ An ISO class 5 cleanroom (B&PC 4127.7[b]); and

☐☐☐ A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility & Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired pursuant to (CCR 1751.4) are allowed in the cleanroom. (CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Yes No N/A

☐☐☐ Compounding, filling, and labeling of sterile injectable compounds;

☐☐☐ Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

☐☐☐ Equipment and supplies;

☐☐☐ Training of staff in preparation of sterile injectable products;

☐☐☐ Training of patient and/or caregiver in the administration of compounded sterile injectable products;

☐☐☐ Procedures for the handling and disposal of cytotoxic agents;

☐☐☐ Quality assurance program; and

☐☐☐ Record keeping requirements.

Yes No N/A

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.02 [b])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

☐☐☐ Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

☐☐☐ All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

☐☐☐ Competency evaluation;

☐☐☐ Storage and handling of products and supplies;

☐☐☐ Storage and delivery of final products;

☐☐☐ Process validation;

☐☐☐ Personnel access and movement of materials into and near the controlled area;

☐☐☐ Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

☐☐☐ A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐☐☐ Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐☐☐ For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐☐☐ Sterilization; and

☐☐☐ End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

Yes	No	N/A	
☐	☐	☐	Telephone number of the pharmacy, unless dispensed for a hospital in-patient;
☐	☐	☐	Name and concentrations of ingredients contained in the product;
☐	☐	☐	Instructions for storage and handling; and
☐	☐	☐	A special label which states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record Keeping Requirements

Yes	No	N/A	
☐	☐	☐	Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])
☐	☐	☐	Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])
☐	☐	☐	The training and competency evaluation of employees in sterile product procedures;
☐	☐	☐	Refrigerator and freezer temperatures;
☐	☐	☐	Certification of the sterile compounding environment;
☐	☐	☐	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);
☐	☐	☐	Inspection for expired or recalled pharmaceutical products or raw ingredients; and
☐	☐	☐	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
☐	☐	☐	The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.4[a])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used:

☐☐☐ Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

☐☐☐ Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])

☐☐☐ No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

☐☐☐ Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

☐☐☐ Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

Yes No N/A

☐☐☐ Aseptic technique;

☐☐☐ Pharmaceutical calculations and terminology;

☐☐☐ Sterile product compounding documentation;

☐☐☐ Quality assurance procedures;

☐☐☐ Proper gowning and gloving technique;

☐☐☐ General conduct in the controlled area;

☐☐☐ Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐☐☐ Sterilization techniques; and

☐☐☐ Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751[e][2])

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751[e][2])

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

☐☐☐ Cleaning and sanitization of the parenteral medication preparation area;

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

☐☐☐ The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐☐☐ Steps to be taken in the event of a drug recall; and

☐☐☐ Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3]).

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Non-Sterile Drug Products

a. Compounding Unapproved Drugs for Prescriber Office Use (CCR 1716.1):

Yes No N/A

☐☐☐ Pharmacy compounds unapproved drugs for prescriber office use based upon a reasonable quantity

☐☐☐ Establishing reasonable quantity is based on the intended use of the compounded medication and nature of the prescriber's practice.

☐☐☐ Compounded medications means medications actively compounded by the pharmacy supplying them to a prescriber.

☐☐☐ Prescriber office use means application or administration in the prescriber's office or for distribution of not more than a 72 hour supply to the prescriber's patients as estimated by the prescriber.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Record Keeping Requirements – Compounding for Future Furnishing (CCR1716.2)

Yes No N/A

☐☐☐ For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

☐☐☐ The date of preparation (compounding);

☐☐☐ The name of the manufacturer, the lot number of all components used to compound the product;

☐☐☐ The expiration date of each component (if not available, the source and date of purchase)

Yes No N/A

☐☐☐ A pharmacy lot number or identification number;

☐☐☐ A master formula for each compounded drug product in a readily retrievable form to also include:

☐☐☐ The amount of each component, compounding directions, etc;

☐☐☐ A beyond-use-date not to exceed 180 days or the shortest expiration date of any component (unless the pharmacy possesses stability data for each product compounded by the pharmacy beyond the 180 days);

☐☐☐ The signature/initials of the person(s) who compounded the drug product; and

☐☐☐ The signature/initials of the pharmacist who checked the final product.

☐☐☐ The final quantity of drug product compounded (number of individual units by weight or volume and package size);

☐☐☐ Status/disposition of any quarantined compounded drug products to also include release date; and

☐☐☐ Status/disposition of any compounded drug products that failed to meet standards for quality purity or strength.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. NUCLEAR PHARMACY

Yes No N/A

☐☐☐ All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ The pharmacy possesses a current Sterile Compounding Permit (B&P 4127) and is compliant with CCR 1751. (must also complete section 21)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
fax: (916) 327-6308
www.pharmacy.ca.gov

California Pharmacy Law
May be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

Medical Board of California
1430 Howe Avenue
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

The **Drug Enforcement Administration** may be contacted at:

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA - Sacramento
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
(909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402

DEA – San Diego
4560 Viewridge Avenue
San Diego, CA 92123-1637
(858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
(510) 637-5600

DEA – San Jose
One North First Street, Suite 405
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

HOSPITAL PHARMACY SELF-ASSESSMENT

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed also.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date:_____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily*_____ *Sat*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

1. _____ RPH # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy Staff (continued): (Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

17. _____ TCH # _____ Exp. Date: _____

18. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes	No	N/A	
☐	☐	☐	The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4117, CCR 1714)
☐	☐	☐	The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 24 – "Compounding Sterile Injectable Drugs")

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Nursing Stations

Yes No N/A

☐☐☐ Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ The pharmacist is responsible for the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Delivery of Drugs

Yes No N/A

☐☐☐ Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

☐☐☐ The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

☐☐☐ Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

☐☐☐ The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

☐☐☐ The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

☐☐☐ The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Drug Stock

Yes No N/A

☐☐☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q])

☐☐☐ All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710)

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the exemptee-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709[c])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4051, CCR 1793.1)

☐☐☐ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052(b). (B&PC 4027, 4051, 4052)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4114, CCR 1726, 1727)

☐☐☐ All prescriptions filled or refilled by an intern are initialed by a pharmacist prior to dispensing. (CCR 1717[b][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐☐☐ The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

Yes No N/A

☐☐☐ Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist. (CCR 1793.7)

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

10. Pharmaceutical Service Requirements

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

Yes No N/A

☐☐☐ Basic information concerning investigational drugs and adverse drug reactions;

☐☐☐ Repackaging and compounding records;

☐☐☐ Physician orders;

☐☐☐ Wards, nursing stations and night stock medications;

☐☐☐ Drugs brought into the facility by patients for storage or use;

☐☐☐ Bedside medications;

Yes No N/A

☐☐☐ Emergency drug supply;

☐☐☐ Pass medications;

☐☐☐ Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;

☐☐☐ Routine distribution of inpatient medications;

☐☐☐ Preparation, labeling and distribution of IV admixtures and cytotoxic agents;

☐☐☐ Handling of medication when pharmacist not on duty; and

☐☐☐ Use of electronic image and data order transmissions.

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

☐☐☐ Destruction of controlled substances; and

☐☐☐ Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Medication/Chart Order

Yes No N/A

☐☐☐ The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4040, 22 CCR 70263[g])

☐☐☐ A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Labeling and Distribution

Yes No N/A

☐☐☐ Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration.(B&PC 4046)

Yes No N/A

☐☐☐ The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Duration of Drug Therapy

Yes No N/A

☐☐☐ The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐☐☐ Date, location, and participants in the quality assurance review;

☐☐☐ Pertinent data and other information related to the medication error(s) reviewed;

☐☐☐ Findings and determinations;

☐☐☐ Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

Yes	No	N/A	
☐	☐	☐	Prescription records (CCR 4081[a])
☐	☐	☐	Purchase Invoices for all prescription drugs (4081[b])
☐	☐	☐	Biennial controlled substances inventory (21 CFR 1304.11)
☐	☐	☐	U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)
☐	☐	☐	Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
☐	☐	☐	Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
☐	☐	☐	Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)
☐	☐	☐	Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
☐	☐	☐	Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 22, 1988] 503, B&PC 4160)
☐	☐	☐	If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
☐	☐	☐	A controlled substances inventory is completed biennially (every two years). Date completed: _____ (21 CFR 1304.11)
☐	☐	☐	Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
☐	☐	☐	Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
☐	☐	☐	DEA Forms-222 are properly executed. (21 CFR 1305.09)
☐	☐	☐	When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)
☐	☐	☐	Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

PIC Initials

Yes No N/A

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

☐☐☐ Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. After-Hours Supply of Medication

Yes No N/A

☐☐☐ The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (Title 22 CCR 70263[f][2])

☐☐☐ The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Emergency Room Dispensing

A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply (B&PC 4068[a]):

Yes No N/A

☐☐☐ The hospital pharmacy is closed and there is no pharmacist available in the hospital;

☐☐☐ The dangerous drug is acquired by the hospital pharmacy;

☐☐☐ The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

☐☐☐ The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

☐☐☐ The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

☐☐☐ The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

☐☐☐ The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label an prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

Yes No N/A

☐☐☐ Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15. CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Central Fill

Yes No N/A

☐☐☐ Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

- If the answer is yes, name of hospital: _____

☐☐☐ Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

- If the answer is "yes", name of supplying pharmacy: _____
- If the answer to this and the previous question is "no" or "not applicable" go to Section 23.

☐☐☐ Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

There are written policies and procedures in place for:

Yes No N/A

☐☐☐ The assurance that each patient received information regarding each medication given at the time of discharge.

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Yes No N/A

☐☐☐ Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility (B&PC 4074, CCR 1707.2[b][3]); and

☐☐☐ Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐☐☐ Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions (if applicable)

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC Permit # _____ or

Name of accreditation agency _____

The pharmacy has a designated area or cleanroom for the preparation of sterile products that has the following:

☐☐☐ An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom (B&PC 4127.7[a]);

☐☐☐ A positive air pressure differential in the cleanroom that is relative to adjacent areas (B&PC 4127.7[a]);

☐☐☐ An ISO class 5 cleanroom ((B&PC 4127.7[b]);

☐☐☐ A barrier isolator that provides an ISO class 5 environment for compounding ((B&PC 4127.7[c]); and

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility and Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired (pursuant to ((CCR 1751.4) are allowed in the cleanroom. ((CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination. (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Yes No N/A

☐☐☐ Compounding, filling, and labeling of sterile injectable compounds;

☐☐☐ Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

☐☐☐ Equipment and supplies;

☐☐☐ Training of staff in preparation of sterile injectable products;

☐☐☐ Training of patient and/or caregiver in the administration of compounded sterile injectable products;

☐☐☐ Procedures for the handling and disposal of cytotoxic agents;

☐☐☐ Quality assurance program; and

☐☐☐ Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. ((CCR 1751.02 [b])

PIC Initials

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Yes No N/A

☐☐☐ Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

☐☐☐ All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

☐☐☐ Competency evaluation;

☐☐☐ Storage and handling of products and supplies;

☐☐☐ Storage and delivery of final products;

☐☐☐ Process validation;

☐☐☐ Personnel access and movement of materials into and near the controlled area;

☐☐☐ Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

☐☐☐ A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐☐☐ Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐☐☐ For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐☐☐ Sterilization; and

☐☐☐ End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

☐☐☐ Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Yes No N/A

☐☐☐ Name and concentrations of ingredients contained in the product;

☐☐☐ Instructions for storage and handling; and

☐☐☐ A special label which states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

☐☐☐ The training and competency evaluation of employees in sterile product procedures;

☐☐☐ Refrigerator and freezer temperatures;

☐☐☐ Certification of the sterile compounding environment;

☐☐☐ Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

☐☐☐ Inspection for expired or recalled pharmaceutical products or raw ingredients; and

☐☐☐ Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.4[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used:

Yes No N/A

☐☐☐ Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

☐☐☐ Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])

☐☐☐ No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

☐☐☐ Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

☐☐☐ Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

☐☐☐ Aseptic technique;

☐☐☐ Pharmaceutical calculations and terminology;

☐☐☐ Sterile product compounding documentation;

☐☐☐ Quality assurance procedures;

Yes No N/A

☐☐☐ Proper gowning and gloving technique;

☐☐☐ General conduct in the controlled area;

☐☐☐ Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐☐☐ Sterilization techniques; and

☐☐☐ Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months.

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

☐☐☐ Cleaning and sanitization of the parenteral medication preparation area;

Yes No N/A

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

☐☐☐ The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐☐☐ Steps to be taken in the event of a drug recall; and

☐☐☐ Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3])

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
fax: (916) 327-6308
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

The **Drug Enforcement Administration** may be contacted at:

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA - Sacramento
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
(909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402

DEA – San Diego
4560 Viewridge Avenue
San Diego, CA 92123-1637
(858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
(510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
(408) 291-7235

Attachment 4

Comments Received Pursuant to the 45-Day Initial Public Notice for the Board's 2004 Omnibus Rulemaking

Virginia Herold
11/15/2004 12:40 PM

To: Robert Grimm/Pharmacy/DCANotes@DCANotes
cc:
Subject: Re: BOP Title 16 Proposed Changes

Thanks Bob,

I will note that we need to catch this correction in the rulemaking file as well.

Giny

Robert Grimm

Robert Grimm
11/14/2004 11:18 AM

To: Virginia Herold/Pharmacy/DCANotes@DCANotes
cc:
Subject: BOP Title 16 Proposed Changes

Hi GInny:

See 1745. Partial Filling of Schedule II prescriptions.

Para (c) (2) delete the word triplicate.

Bob Grimm.

"Richard Abood"
<rabood@pacific.edu
>

11/23/2004 03:08 PM

To: <Virginia_Herold@dca.ca.gov>
cc:
Subject: Comment to proposed reg. 1745

Virginia,

Please consider this comment regarding proposed regulation 1745:

Although those of us who know federal and state pharmacy law will have no problem understanding that paragraph (c) applies to SNF and terminally ill patients and proposed paragraph (d) applies to patients other than SNF and the terminally ill, others will most likely be confused. I would propose that paragraph (c) be rewritten to make reference to paragraph (a). This can be accomplished by simply changing the first sentence of paragraph (c) to add the words "pursuant to paragraph (a)" or perhaps "as defined in paragraph (a)".

(c) When partially filling a prescription pursuant to paragraph (a), ...

If you have any questions, please contact me. Thank you.
Sincerely,
Dick Abood

Richard R. Abood, R.Ph., J.D.
Professor Pharmacy Practice
(209) 946-3155
rabood@pacific.edu