

Regulation Attachment 1

Approved by the Office of Administrative Law 3/13/13
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§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) 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).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate 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) after unprotected intercourse.

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

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

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) 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.

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

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

(8) EC Product Selection: The pharmacist will provide emergency contraception medication 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 containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) 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.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

<i>Brand</i>	<i>Dose</i>	<i>Ethinyl Estradiol per dose (mcg)</i>	
<i>One Tablet Regimens</i>			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel

<i>Two Tablet Regimens</i>			
Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

Oral Contraceptive Pills

<i>Brand</i>	<i>Tablets per Dose (two doses 12 hours apart*)</i>	<i>Ethinyl Estradiol per dose (mcg)</i>	<i>Levonorgestrel per dose (mg)*</i>
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

<i>Non-Prescription Drugs</i>	<i>Dose</i>	<i>Timing of Administration</i>
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 EC 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: Sections 4052 and 4052.3, Business and Professions Code.

Regulation Attachment 2

**Order of Adoption
Board of Pharmacy
California Code of Regulations**

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code 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 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 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~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

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

(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: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

Regulation Attachment 3

Order of Adoption
Board of Pharmacy
California Code of Regulations

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

Regulation Attachment 4

1 **Title 16. Board of Pharmacy**
2 **Proposed Language**
3

4 **To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to**
5 **read as follows:**

6 **§ 1732.05. Accreditation Agencies for Continuing Education.**

7 (a) The following organizations are approved accreditation agencies:

8 (1) The Accreditation Council for Pharmacy Education.

9 (2) The ~~Pharmacy Foundation of California~~ [California Pharmacists Association](#).

10 (b) Accreditation agencies shall:

11 (1) Evaluate each continuing education provider seeking accreditation in accordance with the
12 provider's ability to comply with the requirements of section 1732.1 of this Division.

13 (2) Maintain a list of the name and address of the person responsible for the provider's continuing
14 education program. The accreditation agency shall require that any change in the responsible person's
15 identity shall be reported to the accreditation agency within 15 days of the effective date of the
16 change.

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

18 (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any
19 of its accredited providers or their coursework.

20 (5) Review at least one course per year offered by each provider accredited by the agency for
21 compliance with the agency's requirements and requirements of the board and, on request, report the
22 findings of such reviews to the board.

23 (6) Take such action as is necessary to assure that the continuing education coursework offered by its
24 providers meets the continuing education requirements of the board.

25 (7) Verify the completion of a specific continuing education course by an individual pharmacist upon
26 request of the board.

27 (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers
28 as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation
29 agency by the board.

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

34 **To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
35 **as follows:**

36 **§ 1732.2. Board Accredited Continuing Education**
37

38 (a) Individuals may petition the board to allow continuing education credit for specific coursework
39 which is not offered by a provider but meets the standards of Section 1732.3.

40 (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance
41 to pharmacy practice and has been approved for continuing education by the Medical Board of
42 California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the
43 Dental Board of California shall, upon satisfactory completion, be considered approved continuing
44 education for pharmacists.

45 (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing
46 the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to
47 section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of
48 continuing education for conducting a review of exam test questions. A subcommittee member shall
49 not receive continuing education hours pursuant to this subdivision if that subcommittee member
50 requests reimbursement from the board for time spent conducting a review of exam test questions.

51 (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six
52 hours of continuing education per renewal period. The board shall designate on its public agenda
53 which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician
54 requesting continuing education pursuant to this subdivision must sign in and out on an attendance
55 sheet at the board meeting that requires the individual to provide his or her first and last name, license
56 number, time of arrival and time of departure from the meeting.

57 (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be
58 awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician
59 requesting continuing education hours pursuant to this subdivision must sign in and out on an
60 attendance sheet at the committee meeting that requires the individual to provide his or her first and
61 last name, license number, time of arrival and time of departure from the meeting.

62 (f) An individual may be awarded three hours of continuing education for successfully passing the
63 examination administered by the Commission for Certification in Geriatric Pharmacy.
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65 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
66 Business and Professions Code.

67 **To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
68 **as follows:**

69 **§ 1732.5. Renewal Requirements for Pharmacist.**
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71 (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this
72 Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the
73 board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

74 (b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or
75 more of the following subject areas:

76 1. Emergency/Disaster Response

77 2. Patient Consultation

78 3. Maintaining Control of a Pharmacy's Drug Inventory

79 4. Ethics

80 5. Substance Abuse

81 Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the
82 requirements of this subdivision.

83 ~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion
84 of a continuing education course.

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86 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and
87 4232, Business and Professions Code.

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100 **To Add § 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:**

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102 **§ 1751.9. Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products**

103 (a) An agency seeking to become an approved accrediting agency for pharmacies or nonresident
104 pharmacies that compound sterile injectable drug products pursuant to Business and Professions Code
105 sections 4127.1 or 4127.2 shall submit evidence satisfactory to the board as described in
106 subdivision (b) that:

107 (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited
108 pharmacy at least annually. Site inspections shall be conducted to ensure compliance with Article 4.5
109 (commencing with Section 1735) and Article 7 (commencing with Section 1751) of Division 17 of
110 Title 16 of the California Code of Regulations governing the compounding of sterile injectable drug
111 products.

112 (2) The standards for granting accreditation shall reflect the Pharmacy Law.

113 (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the
114 professional practices subject to accreditation. At least one member of the survey team must be a
115 licensed pharmacist. All health care practitioner surveyors must maintain current, active and
116 unrestricted licensure to practice their respective professions.

117 (4) The accrediting agency has sufficient personnel and resources to accredit California and non-
118 resident pharmacies.

119 (5) The accrediting agency has been operating for a minimum of two years with a history of
120 accrediting health care facilities.

121 (6) The accrediting agency shall provide the board access to an approved accrediting agency's report
122 on individual pharmacies for a three-year period following issuance of the report. Upon request of the
123 board, the agency shall provide the report within 10 business days.

124 (b) An agency seeking approval from the board must submit a formal written request to the board
125 signed by an authorized representative that includes the applicant owner's name, the company name,
126 address of record, and contact information along with the following information:

127 (1) A side-by-side comparison showing the agency's sterile compounding standards and describing
128 how each standard complies with each of the requirements of this Section.

129 (2) A list of employees performing survey inspections that also sets forth the name, title, license
130 number, license type, state of licensure and licensure status for each employee.

131 (3) A list of payers or organizations that the agency is recognized by, if applicable.

132 (4) A list of health care facility sites currently accredited by the agency including the name, location,
133 license type and license number of each site.

134 (5) A detailed description of the process used to evaluate health care facility sites seeking
135 accreditation or reaccreditation.

136 (6) Documentation of compliance with the requirements listed in the self-assessment form referenced
137 in section 1735.2(j) of Title 16 of the California of Code of Regulations in evaluating pharmacies and
138 non-resident pharmacies.

139 (7) Documentary or other evidence of a process to address non-compliance that may include any or
140 all of the following: (a) a requirement for correction of any identified deficiencies within a set
141 timeframe; (b) a requirement that failure to comply shall result in the accrediting agency issuing a
142 reprimand or suspending or revoking the accreditation; or, (c) a process for suspending or revoking the
143 licensed sterile injectable drug compounding pharmacy's accreditation.

144 (c) The Board of Pharmacy shall take action on a completed application at a scheduled board meeting,
145 as follows:

146 (1) If granted, the approval shall be valid for three years from the date of action by the board.

147 (2) If the approval is denied, the agency will be notified of the basis for the denial, including a
148 description of the standards that were not met. The agency may submit additional information to the
149 board for reconsideration of the denial within 30 days of the date of the notice of denial. The
150 reconsideration shall be considered at a scheduled board meeting and the accrediting agency may
151 show compliance with the standards set forth in this Section by producing new documentary evidence,
152 providing testimony or submitting other evidence demonstrating why the approval should be granted.

153 (d) After approval, an approved accreditation agency shall continue to meet the standards provided in
154 this Section and meet any conditions under which it is approved by the board. Failure to comply with
155 the standards set forth in this section or any conditions set by the board shall be grounds for rescission
156 of the board's approval.

157 (e) The accreditation agency shall, within 24 hours, report to the board any licensed sterile injectable
158 drug compounding pharmacy issued a reprimand or any licensed sterile injectable drug compounding
159 pharmacy whose accreditation has been suspended, revoked, or otherwise restricted by the
160 accrediting agency.

161 (f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a
162 report to the board listing all board-licensed pharmacies or nonresident pharmacies that are currently
163 accredited and have been accredited during the past 12 months with a notation of the outcome of
164 each inspection conducted by the accrediting agency.

165 (g) The board may conduct unannounced inspections of accredited sites to determine if the licensed
166 facility is in compliance with the Pharmacy Law. An accrediting agency shall cooperate with any board
167 investigation or inspection conducted by the board.

168 (h) Three months before the end of an approval or re-approval period, an approved accrediting
169 agency must submit a formal, written request for re-approval to the board or its designee for
170 continued recognition as an approved accrediting agency. The re-approval request shall provide the
171 information set forth in subdivision (b). If the re-approval application fails to demonstrate compliance
172 with this Section, or the board has evidence that the accrediting agency has failed to meet the
173 requirements of this section, the Board or its designee may issue and serve a notice of denial of re-
174 approval on the accrediting agency at its address of record with the board. The denial shall set forth
175 the factual and legal basis for the denial. Within 30 days of the date of the notice, the accrediting
176 agency may request an appeal of the decision to deny re-approval. If no appeal is requested, the
177 denial shall become final. If the board receives a request for an appeal of the notice, the request for an
178 appeal shall be considered a request for an informal hearing under the Administrative Procedure Act
179 (commencing with Section 11445.10 of the Government Code).

180 (i) Recognition of an approval shall continue pending the outcome of any appeal from a notice of
181 denial or rescission of any approval. However, if either a denial or rescission of an approval is upheld
182 after appeal, the accrediting agency shall notify all affected pharmacies or nonresident pharmacies of
183 the loss of the board's approval.

184 (j) The board may evaluate the performance of an approved accreditation agency and may rescind its
185 approval of the accreditation agency for failure to conform with the Pharmacy Law and standards
186 relating to sterile injectable drug compounding or any of the provisions of this section. The Board or its
187 designee may issue and serve a notice of rescission of approval on the accrediting agency at its address
188 of record with the board. The rescission notice shall set forth the factual and legal basis for the
189 rescission and set forth the process for appealing the notice. Within 30 days of the date of the notice,
190 the accrediting agency may request an appeal of the decision to rescind approval. If no appeal is
191 requested, the denial shall become final. If the board receives a request for an appeal of the notice,
192 the request for an appeal shall be considered a request for an informal hearing under the
193 Administrative Procedure Act (commencing with Section 11445.10 of the Government Code).

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195 Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:
196 Section 4127.1, Business and Professions Code.