

## TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (“Board”) 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 May 6, 2015.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the 45-day written comment period.

The Board, upon its own motion or at the insistence 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: Under the authority conferred by Business and Professions Code §4005, in order to implement, interpret and make specific Business and Professions Code §4005, §4231, and §4300, the Board is proposing to amend Articles 2 and 10 of Division 17 of Title 16 of the California Code of Regulations (“CCR”), as follows:

### INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Board proposes to amend §1715 and §1784 of Articles 2 and 10 of Division 17 of Title 16 of the California Code of Regulations to update and improve the self-assessment forms that pharmacies and wholesalers are required to complete (Form 17M-13, Form 17M-14, and Form 17M-26).

### Revise and Update Three Self-Assessment Forms

16 CCR §1715 requires a pharmacist-in-charge (PIC) of a pharmacy licensed under Business & Professions Code (“B&P”) §4029 or §4037 to complete a self-assessment before July 1 of every odd-numbered year, and within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the PIC, and he or she becomes the new PIC of a pharmacy. The self-assessment forms are essentially a compilation of relevant laws that apply to community, hospital and compounding pharmacies licensed by the Board. When a PIC goes through the self-assessment form biennially, this helps insure the pharmacy’s operations conform to statutory and regulatory requirements, and makes the pharmacy site inspection process more meaningful by providing useful information about controlling statutes and regulations. Self-assessment forms also serve as an easy reference guide for a Pharmacist-in-Charge (“PIC”).

16 CCR §1784 requires the Designated Representative-in-Charge (“DRIC”) of a wholesaler to complete a self-assessment before July 1 of every odd-numbered year, or within 30 days of (1)

a new wholesaler permit being issues; (2) when there is a change in the DRIC, and (3) when there is a change in the licensed location of a wholesaler to a new address. This self-assessment form assists wholesalers in improving their compliance with legal requirements. The self-assessment also makes the pharmacy inspection process more meaningful and provides relevant information to wholesalers and the DRIC.

### **Amend 16 CCR §1715**

16 CCR §1715 makes reference to two forms, Form 17M-13 “*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*” (Rev. 01/11) and Form 17M-14 “*Hospital Pharmacy Self-Assessment*” (Rev. 01/11). The proposed amendment of 16 CCR 1715 seeks to update both of the incorporated forms. To accomplish this, along with making changes in the forms themselves, 16 CCR§1715 must be amended so that where the forms are incorporated by reference the date of the latest revision must be updated. Thus, within 16 CCR §1715 the notation (Rev. 10/14) must be substituted for the previous revision date (Rev. 01/11) on both Form 17M-13 and 17M-14.

**FORM 17M-13:** The Board proposes changes that both remove out-of-date material and add new sections, items, and sub-paragraphs to set out new law and regulations in Form 17M-13 “*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment.*” The new law added to this self-assessment is summarized as follows: The Board is adding a specific requirement that pharmacies must be properly lighted, and free from rodents and insects. The Board is removing the word “injectable” from the phrase “sterile injectable drugs” so that the wording is consistent with pending compounding regulations which cover not only injectables, but also cover sterile compounded drugs which are applied in the eye or nose, or inhaled into the lungs.

The Board is shortening the notice period, from within 30 days to within 14 days for when a pharmacy must notify the Board of any licensed individual’s admission of theft, diversion or self-use of dangerous drugs, or of chemical, mental or physical impairment affecting their ability to practice. This notice period is similarly shortened for when a pharmacy must notify the Board of receipt of video or documentary evidence of impairment of a licensed individual or of theft, diversion, or self-use of dangerous drugs by a licensed individual. The notice period is also shortened for when a pharmacy terminates a licensed individual for chemical, mental or physical impairment affecting a licensed individual’s ability to practice, or the termination of a licensed individual based on theft, diversion or self-use of dangerous drugs. New language is being added to insure the PIC takes responsibility for insuring that all dangerous drugs and devices are not being adulterated, and/or misbranded, and are not expired.

New sections are added to provide guidance in dealing with Voluntary Drug Repository and Distribution (“VDRD”) Programs. Pharmacies that donate drugs to VDRD programs must be licensed by and not on probation with the Board, and their primary or sole type of pharmacy practice must be limited to skilled nursing facility, home health care, board and care or mail order. If the pharmacy utilizes a surplus medication collection and distribution intermediary, it must ensure the intermediary is licensed by the Board. No controlled substances shall be donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident

packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under any conditions other than those set by the USP or the product manufacturer. Drugs which were returned from a health facility where the drugs were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Pharmacies that operate a county-approved VDRD program must be licensed by and not on probation with the Board, must be county owned or contract with the county to establish a VDRD program or be owned and operated by a primary care clinic licensed by the California Department of Public Health. Such pharmacies must provide the date they filed a “notice of intent” to participate in a VDRD program with the county health department, must comply with the county’s established written procedures, and must provide, on a quarterly basis, to the county health department the name and location of all sources of donated medication it receives.

Pharmacies that receive drugs under a VDRD program must segregate all donated medications from the participating entity’s other drug stock by physical means, for purposes that include inventory, accounting and inspection, and records of acquisition and disposition of donated medications must be kept separate from the participating entity’s other drug acquisition and disposition records. The participating pharmacy must follow the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. No controlled substances may be received. Donated medications received must be unused, unexpired and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under conditions other than those set by the USP or the product manufacture. Drugs which were returned from a health facility where the drugs were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Donated medications must be maintained in the donated packaging until dispensed in a new and properly labeled container, specific to the eligible patient, who has presented a valid prescription. Donated medications received in open containers shall not dispensed under the program or transferred to another participating entity; and once identified, must be quarantined immediately and disposed of in accordance with the Medical Waste Management Act. If a pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county, it must have a written agreement outlining the protocols and procedures for the transfer of donated medications. Donated medication must not transferred by any participating entity more than once. When transferring donated medications, documentation must accompany the medication that identifies the drug name, strength, quantity of medication, the donating facility from where

the medication originated, and a statement that the medication may not be transferred to another participating entity.

New items are being added within existing sections which set out new law addressing additional services pharmacists are now able to supply to patients without a prescription from a physician. Pharmacists now need to be able to look up the controlled substance history of a patient in the CURES Prescription Drug Monitoring Program. Pharmacists are now allowed to perform clinical laboratory tests, both those that require CDPH registration and those that do not. An entire new section is added to set out the duties of an Advance Practice Pharmacist ("APP") which include: pharmacists initiating or adjusting a controlled substance therapy must register with the federal Drug Enforcement Administration. An APP may do patient assessments and interpret drug therapy-related tests, refer patients to other health care providers, and collaborate with other health care providers to evaluate and manage diseases and health conditions. An APP may also initiate, adjust, or discontinue drug therapy, and order tests in coordination with a patient's primary provider or diagnosing prescriber, while transmitting information to a record system shared with the patient's primary care provider or diagnosing provider.

A new item is being added to remind pharmacists that intern pharmacists may not perform any discretionary duties nor act as a pharmacist during a temporary absence of a pharmacist on duty free breaks or meal periods. Pharmacists are to supervise only one technician trainee for only 120 hours or less, and that externship pharmacy technician trainees may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist.

Several new items concern labeling, and now the name of the patient, the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed if indicated on the prescription, must be clustered into one area of the label and comprise at least 50 percent of the label. A label must be highlighted in bold typeface or color and use blank space to set off the mandatory information items, and where applicable, standardized directions must be used. A pharmacy must not dispense more than a 90-day supply of a dangerous drug under these circumstances: -where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills, -where the prescriber has not indicated "no change to quantity" or words of similar meaning, -where the patient has completed an initial 30-day supply (not required where the prescription continues the same medication as previously dispensed in a 90-day supply), -where the total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills, -where the prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary, and -where the pharmacist is exercising his or her professional judgment. When dispensing more than a 90-day supply, the pharmacist must notify the prescriber of the increase in quantity dispensed. A pharmacist must include a label on the drug container which indicates the drug may impair a person's ability to operate a vehicle or a vessel.

Internet prescriptions must only be dispensed on a prescription issued pursuant to a good faith prior examination and internet prescriptions for controlled substances are only dispensed if in

compliance with the Ryan Haight Online Pharmacy Consumer Protection Act. All pharmacists must obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice.

New items are being added to the section regarding Record Keeping Requirements, which include when hypodermic needles and syringes are furnished by a pharmacy, or furnished by a Hypodermic Needle and Exchange Program (“HNEP”), without a prescription, the pharmacy or HNEP must provide the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C, and safe disposal of sharps waste; and provide one or more of the following disposal options: -onsite, safe, hypodermic needle and syringe collection and disposal program, -furnish or make available mail-back sharps containers, -furnish or make available sharps containers.

Several items were added to an existing section about epinephrine. A pharmacy dispensing epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care must follow certain record keeping guidelines. A physician/surgeon must provide a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. The pharmacy must label epinephrine auto-injectors with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only” along with the dosage, use and expiration date. Each dispensed prescription must include the manufacturer’s product information sheet for epinephrine auto-injector.

Among other new items, a pharmacy’s DEA-controlled substances inventory form must indicate whether the inventory was taken at the “open of business” or at the “close of business.” When furnishing controlled substances for physician office use, a pharmacist must ascertain that a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner’s general dispensing to patients.

Additional new items concern where a pharmacist must take several steps before dispensing oral or electronically transmitted prescriptions 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. A pharmacist must first reduce the prescription to writing on a pharmacy-generated form, and the licensed facility must provide the pharmacy with a copy of the prescriber’s signed order, when available. The prescription must be endorsed by the pharmacist with the pharmacy’s name, license, and address, and the physician must have signed the original prescription or provides a facsimile signature on the prescription. The pharmacist must also obtain the signature of the person who receives the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. Any computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. Controlled substance prescriptions written with the “11159.2 exemption” for the terminally ill must be only dispensed when the original prescription is received, and was tendered and partially filled within 60 days with no portion dispensed more than 60 days from the date issued.

Electronic prescriptions (e-scripts) for controlled substances which are received by the prescriber must meet federal requirements.

A new section adds standards of service for providers of blood clotting products for home use (“BCPHU”). Pharmacies that provide such products can be a health system pharmacy, a pharmacy affiliated with hemophilia treatment centers, a specialty home care pharmacy or a retail pharmacy. To do so the pharmacy must have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. A pharmacy must dispense BCPHU to a provider that has sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and must know about proper storage and refrigeration of clotting factors, and maintain a 24-hour on-call service 7 days a week, screening telephone calls for emergencies, acknowledging all telephone calls within one hour or less, and providing access to knowledgeable pharmacy staffing on call 24 hours a day.

To provide BCPHU, the pharmacy must be able to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. The pharmacy supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. The pharmacy must store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product’s approved package insert. Upon authorization for a nonemergency prescription, a pharmacy must ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less.

Upon approved authorization to dispense a prescription of BCPHU for an emergency situation, provided manufacturer supply exists, a pharmacist delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. A pharmacy provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. A pharmacy that supplies patients with BCPHU must notify patients dispensed these products about Class 1 and Class 2 recalls and withdrawal of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and the pharmacy must participate in the National Patient Notification System for blood clotting recalls. A pharmacist who supplies BCPHU must provide language interpretive services over the telephone or in person, as needed by the patient, and must have a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations.

Pharmacies that furnish emergency contraceptives (“EC”) must follow the protocol approved by the Board and the Medical Board, and provide the patient with a copy of the current Board-

approved EC Fact Sheet. Pharmacies furnishing EC must maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol. Prior to furnishing EC, a pharmacist must have completed a minimum of one hour of continuing education (“CE”) specific to emergency contraception. Pharmacists who decline to dispense EC or other prescription drug or device pursuant to a conscience clause must notify his or her employer in writing before interacting with members of the public seeking EC. If EC services are not immediately available whether because the mandatory CE has not been completed, or a pharmacist declines to dispense CE pursuant to a conscience clause, the pharmacist must refer the patient to another emergency contraception provider under a protocol that ensures a patient has timely access to the prescribed drug or device.

Pharmacies that furnish naloxone hydrochloride (“Naloxone”), must do so in accordance with the protocol approved by both the Board and the Medical Board of California, which requires providing a fact sheet and a mandatory consultation with the person to whom the drug is furnished. The mandatory consultation must explain opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient. Where possible with the patient’s consent, pharmacists must notify the patient’s primary care provider of any drug or device furnished to the patient, and if that is not possible, enter the appropriate information in a patient record system.

**FORM 17M-14:** The Board proposes changes that both remove out-of-date material and add new sections, items, and sub-paragraphs to set out new law and regulations in Form 17M-14 *“Hospital Pharmacy Self-Assessment.”* The new law is summarized as follows: The Board is inserting language to allow an intern, or pharmacy technician, to complete the monthly inspections of all floor stock and drugs maintained in nursing stations.

The Board is shortening the notice period, from within 30 days to within 14 days for when a pharmacy must notify the Board of any licensed individual’s admission of theft, diversion or self-use of dangerous drugs, or of chemical, mental or physical impairment affecting their ability to practice. This notice period is similarly shortened for when a pharmacy must notify the Board of receipt of video or documentary evidence of impairment of a licensed individual or of theft, diversion, or self-use of dangerous drugs by a licensed individual. The notice period is also shortened for when a pharmacy terminates a licensed individual for chemical, mental or physical impairment affecting a licensed individual’s ability to practice, or the termination of a licensed individual based on theft, diversion or self-use of dangerous drugs.

New items discuss that all unit-dose drugs received from a centralized hospital packaging pharmacy are required to be correctly labeled and barcoded, with the barcode being readable at the patient’s bedside. All drugs must be maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer’s guidelines.

A new section was added to cover hospital pharmacies that donate drugs to Voluntary Drug Repository and Distribution ("VDRD") programs. Those hospitals must be licensed by and not on probation with the Board, and their primary or sole type of pharmacy practice must be limited to skilled nursing facility, home health care, board and care or mail order. No controlled substances shall be donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under any conditions other than those set by the USP or the product manufacturer. Drugs which were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Hospital pharmacies must follow the same procedural drug pedigree requirements for donated drugs as done for drugs purchased from a wholesaler or directly from a drug manufacturer.

An entire new section is being added which sets the duties of an Advance Practice Pharmacist ("APP"). Pharmacists initiating or adjusting a controlled substance therapy must register with the federal Drug Enforcement Administration. An APP may do patient assessments and interpret drug therapy-related tests, refer patients to other health care providers, and participate in the evaluation and management of diseases and collaborate with other health care providers. An APP may initiate, adjust, or discontinue drug therapy, while transmitting information to a record system shared with the patient's primary care provider or diagnosing provider. Pharmacists may order tests in coordination with a patient's primary care provider or diagnosing provider, and must transmit that information to a record system shared with the patient's primary care provider or diagnosing provider.

New items were added that allow Intern pharmacists to stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies, and inspect the drugs maintained in the health care facility at least once per month. Intern pharmacists may not perform any discretionary duties nor act as a pharmacist during a temporary absence of a pharmacist on duty free breaks or meal periods. Pharmacy technicians may, at the discretion of the pharmacist, remain in the pharmacy while the pharmacist is on a duty free break or meal period, but may only perform non-discretionary tasks. Any task performed by a pharmacy technician during the pharmacist's temporary absence must be reviewed by the pharmacist. Pharmacy technician duties are expanded to include packaging emergency supplies for use in the health care facility and the hospital's emergency medical system, sealing emergency containers for use in the health care facility, and performing monthly checks of the drug supplies stored throughout the health care facility and reporting any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer.

New items added to existing sections require that the hospital pharmacy only furnish dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and

protocols established under policies and procedures. Records of centrally stored unused medications donated to a drug repository and distribution program must be kept for three years.

A new section is being added on Centralized Hospital Packaging Pharmacy Practices. A hospital pharmacy may package unit dose medication for the pharmacy for inpatients of one or more hospitals under common ownership within a 75-mile radius: The pharmacy must prepare and store limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. All unit dose medications produced by a centralized hospital packaging pharmacy must be barcoded and readable at the inpatient's bedside. The barcode information must contain: the date the medication was prepared, the components used in the drug product the lot number or control number, the expiration date, the National Drug Code Directory number, and the name of the centralized hospital packaging pharmacy. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

#### **Amend 16 CCR §1784**

16 CCR §1784 should be amended so that where it incorporates by reference Form 17M-26 "*Wholesalers of Dangerous Drugs and Devices Self-Assessment* (Rev. 01/11)" the reference to the last update of the form is changed to read (Rev. 10/14).

**Form 17M-26:** The Board proposes changes that both remove out-of-date material and add new sections, items, and subparagraphs set out new laws and regulations in Form 17M-26 "*Wholesalers of Dangerous Drugs and Devices Self-Assessment.*" The new law is summarized below. Language was added requiring that the designated representative-in-charge must be at least 18 years of age to be responsible for the wholesaler's compliance with all applicable laws. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site.

An entire new section was added specifying the requirements to participate in voluntary drug repository and distribution ("VRDR") programs. Wholesalers may donate medications to a county-approved VRDR program, provided no controlled substances are donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been stored under conditions that comply with the standards set by USP or the product manufacturer. Drugs must have never been in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law.

A new item was added to note the change in federal law that requires, for controlled substances, that the biennial inventory record document must indicate that the inventory was taken at the “close of business” or “opening of business.”

**Specific Benefits Anticipated:** This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances. This regulatory proposal benefits workers’ safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work. This regulatory proposal does not affect the state’s environment because it simply brings up-to-date mandatory forms which PICs and DRICs already must complete biennially.

While the Board website has updated versions of all three Self-Assessment Forms available for licensees to use, those updated versions have not been through the formal rulemaking process. All changes to the self-assessment forms incorporated by reference in the regulations herein are to be made to the 2011 version of each form, versions formally adopted through the rulemaking process. Superseded or deleted law and regulations are being removed, and new sections, items and sub-paragraphs are added to three self-assessment forms. There are also a number of common non-substantive changes on all three forms. Self-assessments do not impose the new laws. PICs and DRICs are already obligated to comply with new laws and regulations, and the self-assessment form is simply a tool provided by the Board to aid them in doing so. All of the proposed changes, taken together, work to reassure PICs and DRICs that the information and references contained in the forms are current as of the new revision date.

**Consistency with and Compatibility with Existing State Regulations:** During the process of reviewing and revising the regulations, and amending the self-assessment forms incorporated by reference in §1715 and §1784, the Board has conducted a search of any similar regulations on this topic and has determined that those two regulations, along with regulations concerning compounding and the Compounding Self-Assessment Form, are the only regulations which deal with the Board’s mandate requiring pharmacies and wholesalers to conduct self-assessments. The compounding regulations are presently being revised through the formal rulemaking process, and thus the Compounding self-assessment form is not the subject of this update. These proposed revisions and amendments to §1715 and §1784, and the forms incorporated by reference therein, are consistent and compatible with existing state regulations.

**Forms Incorporated by Reference:** 16 CCR §1715 incorporates by reference both Form 17M-13 “*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*” (Rev. 01/11) and Form 17M-14 “*Hospital Pharmacy Self-Assessment*” (Rev. 01/11). 16 CCR §1784 incorporates by reference Form 17M-26 “*Wholesaler Dangerous Drugs & Devices Self-Assessment*” (Rev. 01/11).

**Mandate on Local Agencies or School Districts:** This regulatory action does not impose a mandate on local agencies or school districts.

## **FISCAL IMPACT**

- A. Cost or savings to any state agency: NONE
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- D. Other nondiscretionary cost or savings imposed to local agencies: NONE
- E. Cost or savings in federal funds to the state: NONE

### **Effect on Housing Costs:** NONE

**Business Impact:** The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact on directly affected businesses, including the ability of California businesses to compete with businesses in other states.

**Results of Economic Impact Assessment:** While this regulatory proposal affects pharmacies and wholesalers, it will not have a significant statewide adverse economic impact directly affecting business, or businesses' ability to compete.

**Impact on Jobs/New Businesses:** The Board has determined that the regulatory proposals herein will not have any impact on the creation or elimination of jobs, of the creation of new businesses or the elimination of existing businesses, or the expansion of businesses in the State of California.

**Benefits of the Regulations:** This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances. This regulatory proposal benefits workers' safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work. This regulatory proposal does not affect the state's environment because it simply brings up-to-date mandatory forms the PICs and DRICs already must complete biennially.

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

**Business Report:** The proposed regulations do not require a new report to be made. The proposed regulations simply improve, by revising and updating, existing forms that PICs and DRICs must already fill out biennially and when certain enumerated conditions occur. Full compliance by pharmacies and wholesalers with laws and regulations will help insure the health and welfare of all CA residents and help to create a safer work environment for pharmacy and wholesaler employees.

**Effect on Small Businesses:** The Board has determined that the proposed regulations would not affect small businesses. The Board already requires pharmacists and wholesalers to

complete a self-assessment every two years, so the Board finds that correcting and updating the forms used to conduct self-assessments will have no impact on small businesses.

**CONSIDERATION OF ALTERNATIVES:** The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations to the Board at the address listed for the Contact Person.

**INITIAL STATEMENT OF REASONS AND INFORMATION:** The Board of Pharmacy has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

**TEXT OF PROPOSAL:** Copies of the exact language of the proposed regulations, and any document incorporated by reference, 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 person designated below as contact person, or by accessing the Board of Pharmacy's Web site at [http:// www.pharmacy.ca.gov](http://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 Board of Pharmacy's Web site [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

**CONTACT PERSON:** Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

Board of Pharmacy  
Attn: Karen Halbo  
1625 N. Market Blvd., N219  
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(Backup contact person)  
Board of Pharmacy  
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