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Legislation and Regulation Committee

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LEGISLATION REPORT AND ACTION

A. Board Sponsored Legislation –Information Only

AB 977 (Skinner) – Pharmacists: Immunization Administration – Proposal to Add §4052.8 to the Business and Professions Code

ATTACHMENT A

Last year, the board approved a legislative proposal to expand the conditions under which a pharmacist could administer certain immunizations. This proposal also strengthened the training requirements for such pharmacists and established reporting requirements. The proposal, as introduced, was defeated early on because of strong objections by the California Medical Association (CMA) and was significantly amended to only include intent language. In early December, board staff resumed work on this proposal and provided amendments to the author's office for consideration. The amendments resulted in a scaled-back version of the original proposal, but still provided improved patient access to life-saving flu vaccinations. While still in draft form, staff was advised that, with a few amendments, CMA will no longer oppose the bill. The author accepted CMA amendments at the January 5, 2010, Assembly Health Committee hearing, and it was again amended on January 6, 2010 to correct drafting errors. The bill subsequently passed out of Assembly Business and Professions Committee on January 12, 2010. Having passed out of the house of origin, the bill will next be assigned for hearing in the Senate.

A copy of the January 6, 2010, version of the bill is provided in Attachment A.

B. For Possible Action: Proposals for Board-Sponsored Legislation

1. AB 1370 (Solorio) – Centralized Hospital Drug Distribution – Proposal to Add Article 7.6 section 4128 Business and Professions Code

ATTACHMENT B-1

During the October Board Meeting, the board heard presentations by technology vendors as well as hospital systems representatives regarding the technology available to centralize some pharmacy related functions, including the packaging of items into unit dose as well as preparation of compounded medicine. Since that meeting, board staff has provided technical assistance to Assembly Member

Solorio's office in the drafting of language that would enable hospitals under a common ownership to establish one pharmacy under which they would prepare unit dose medications for all of the hospitals' pharmacies. A copy of the measure is attached for the board's consideration.

Recommendation

Approve AB 1370 proposal for sponsorship in future legislation

2. Reverse Distributors – Proposal to Specify the Operations of Reverse Distributors

ATTACHMENT B-2

Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. Should the board vote to pursue sponsorship of such legislation, the following provisions could be included in an omnibus bill.

- a. Amend section 4040.5 – Reverse Distributor
Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines “dispensed” for purposes of this section only. This provision was approved in concept only by the board in January 2009.
- b. Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines “licensed integrated waste hauler” for purposes of this section only. This provision was approved in concept only by the board in January 2009.
- c. Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy
Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. (Language for the later provision will require development.) This provision has not previously been considered by the board.

Recommendation

Approve reverse distributor proposal for inclusion in an existing bill, possibly SB 26 (Simitian)

3. Omnibus Proposal #1 (Senate Business, Professions and Economic Development Committee)

ATTACHMENT B-3

Recommendation

Approve the following provisions for inclusion in a 2010 Omnibus bill.

- a. §4196(e) – Veterinary Food Animal Drug Retailer; Designated Representative in Charge
At its October 2008 Board Meeting, the board approved provisions to be include in the 2009 Omnibus Bill (Senate BP&ED, SB 821). The chaptered version of SB 821 contained a drafting error and the section requires clarification (to be amended as previously approved by the board).
- b. §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x failure)
In October 2008, the board approved that the sunset provision within §4200.1 be eliminated. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has, again, been proposed to the Senate BP&ED Committee for inclusion in the 2010 Omnibus bill.
- c. §4362 – Pharmacists Recovery Program; Administrative Co-Pay
The board approved in October 2008 the proposal to add section 4362 to the Business and Professions Code to establish a co-pay for participants in the Pharmacists Recovery Program to offset a portion of the board's administrative fee for each participant. That proposal was not picked up for inclusion in the Senate BP&ED 2009 Omnibus bill. The board will again pursue the addition of §4362 through a 2010 Omnibus bill.

4. Omnibus Proposal #2 (Senate Business, Professions and Economic Development Committee)

ATTACHMENT B-4

Recommendation

Approve the following provisions for inclusion in a 2010 Omnibus bill.

Amendments to the Department's general B&P provisions -- sections 650.1 and 651 – as reflected on the agenda – were not included in the board's proposal to Senate BP&ED.

Amendments to update references to the California Department of Public Health (formerly known as the Department of Health Services) and one amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)

§4017 – Authorized Officers of the Law (references Food and Drug Branch of CDPH)

§4027(c) – References specified health care facilities licensed by CDPH

§4028 – Defines "licensed hospital" and includes any institution classified under regulations issued by CDPH.

§4037 – Defines “Pharmacy.” Subdivision (b) specifies what is not included in the definition of a pharmacy, including specified area(s) inside a facility licensed by CDPH.

§4052.3(e) – Emergency Contraception Drug Therapy; Requirements and Limitations. Subdivision (e) specifies that information provided to the recipient of the emergency contraception drugs be provided on a form that is developed in consultation with the California Department of Public Health and others.

§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions. Subdivision (d) specifies that home dialysis patients who receive drugs, as specified, shall have completed a full course of home training given by a dialysis center licensed by the CDPH, etc. Subdivision (f) requires update to reflect the reference to the Physical Therapy Board of California.

§4072(b) – Oral or Electronic Transmission of Prescription – Health Care Facility. Subdivision (b) affirms the role of the CDPH in regulating drug order processing requirements for licensed health care facilities as specified.

§4119(a) – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies. Subdivision (a) provides that a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility, as specified, in accordance with regulations of the CDPH as set forth in Title 22 and the requirements as set forth in §1265.1 of the Health and Safety Code, etc.

§4127.1(d) – License to Compound Injectable Sterile Drug Products Required. Subdivision (d) specifies that pharmacies operated by entities that are licensed by either the board or the CDPH and that have current accreditation, as specified, are exempt from the requirement to obtain a license pursuant to §4127.1.

§4169 – Prohibited Acts. Subdivision (d) states that this section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the CDPH. Subdivision (c) identifies an operative date of 2008.

§4181(a) – License Requirements; Policies and Procedures; Who May Dispense. Provides that a clinic, licensed under §4180 (nonprofit or free clinics) shall comply with all applicable laws and regulations of the CDPH relating to drug distribution.

§4191(a).- Compliance with California Department of Public Health; Who May Dispense Drugs. Provides that prior to the issuance of a clinic license under this article (surgical clinics), the clinic shall comply with all applicable laws and regulations of the CDPH and the board relating to drug distribution, etc.

Amendments to update references to the Department of Health Care Services (formerly known as the Department of Health Services)

§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring. Subdivisions (b) (c) and (d) reference DHCS as it relates the calculation and transmission of Medi-Cal pricing to the pharmacy.

§4426 – California Department of Health Care Services to Study Reimbursement Rates. This section specifies that the DHCS shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates.

C. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. Department of Consumer Affairs Enforcement Model Changes

Information Only – No Action Required

2. Changes Proposed by the Board for Addition into DCA's Enforcement Model

ATTACHMENT C-2

At the October 2009 Board Meeting, the board voted to pursue that the following provisions be included in the department-wide enforcement proposals.

- a. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.
- b. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure
Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.
- c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

Recommendation

Pursue changes for sponsorship by the Senate Committee on Business Professions and Economic Development as part of an existing bill or as part of a separate, board-sponsored bill.

D. 2009 Legislation – No action required

Various measures introduced in 2009 were tracked by board staff, and are referenced on the Agenda. No status is being provided on these measures. For copies of those bills, please access the Legislature's Web site at <http://www.leginfo.ca.gov>

Attachment A

*AB 977 (Skinner)
Pharmacists: Immunization Administration
Proposal to Add §4052.8 to the Business and
Professions Code*

AMENDED IN ASSEMBLY JANUARY 6, 2010

AMENDED IN ASSEMBLY JANUARY 4, 2010

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 977

Introduced by Assembly Member Skinner

February 26, 2009

An act to ~~amend Section 4052 of, and to add and repeal Section 4052.8 to,~~ of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 977, as amended, Skinner. Pharmacists: immunization protocols with physicians.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime. Existing law, among other things, authorizes a pharmacist to administer immunizations pursuant to a protocol with a prescriber.

This bill, *until January 1, 2015*, would additionally authorize a pharmacist to initiate and administer influenza ~~and pneumococcal~~ immunizations to any person ~~11~~ 18 years of age or older pursuant to standardized protocols developed and approved by both the board and the Medical Board of California. The bill would require a pharmacist, prior to initiating and administering those immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist initiating and administering

those immunizations to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require a pharmacist, at the time of administration of ~~an~~ *that* immunization, to provide the patient with a Vaccine Information Statement and to provide the patient and the patient’s physician with documentation of administration of the immunization. The bill would also require a pharmacist administering ~~an~~ *that* immunization to maintain a specified immunization record, provide documentation of administration to the appropriate immunization registry, report any adverse event and ~~assure~~ *ensure* proper storage and handling of vaccines. The bill would authorize a pharmacist initiating and administering vaccines *under these provisions* to initiate and administer epinephrine for severe allergic reactions. ~~The bill would also require a pharmacist to obtain the consent of a parent or guardian before administering any immunization to a patient under 18 years of age.~~

This bill would require the board and the Medical Board of California to complete an evaluation of influenza immunizations initiated and administered under the standardized protocols authorized by the bill, and to report to the appropriate policy committees of the Legislature by January 1, 2014.

Because this bill would create new requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Vaccines are a safe, effective, and efficient means to prevent
- 4 sickness and death from infectious diseases as reported by the
- 5 United States Department of Health and Human Services (HHS).

1 ~~(b) The National Vital Statistics Report published by HHS~~
2 ~~reports that influenza and pneumonia combined are the eighth~~
3 ~~leading cause of death in people of all ages, and the sixth leading~~
4 ~~cause of death in people over 65 years of age.~~

5 ~~(c)~~

6 ~~(b) The federal Centers for Disease Control and Prevention~~
7 ~~report that 220,000,000 persons should get the influenza~~
8 ~~vaccination annually, however, fewer than 100,000,000 do.~~

9 ~~(d)~~

10 ~~(c) According to the California Health Care Foundation,~~
11 ~~6,600,000 Californians are uninsured and may not have access to~~
12 ~~immunizations.~~

13 ~~(e)~~

14 ~~(d) Pharmacists represent the third largest health professional~~
15 ~~group in the United States and are on the front line of preventative~~
16 ~~care.~~

17 ~~(f)~~

18 ~~(e) Pharmacists are trained to screen, administer, and properly~~
19 ~~deal with any adverse events that may arise from vaccines.~~

20 ~~(g)~~

21 ~~(f) Primary care physicians play an integral role in preventative~~
22 ~~health care for Californians. This act will provide an adjunct to~~
23 ~~that preventative health care.~~

24 ~~(h)~~

25 ~~(g) Therefore, in order to achieve greater access to immunization~~
26 ~~and to protect Californians, it is the intent of the Legislature to~~
27 ~~provide greater access to lifesaving vaccinations and to ensure that~~
28 ~~pharmacists may independently administer influenza and~~
29 ~~pneumococcal vaccinations.~~

30 ~~SEC. 2. Section 4052 of the Business and Professions Code is~~
31 ~~amended to read:~~

32 ~~4052. (a) Notwithstanding any other provision of law, a~~
33 ~~pharmacist may:~~

34 ~~(1) Furnish a reasonable quantity of compounded drug product~~
35 ~~to a prescriber for office use by the prescriber.~~

36 ~~(2) Transmit a valid prescription to another pharmacist.~~

37 ~~(3) Administer, orally or topically, drugs and biologicals~~
38 ~~pursuant to a prescriber's order.~~

39 ~~(4) Perform procedures or functions in a licensed health care~~
40 ~~facility as authorized by Section 4052.1.~~

1 ~~(5) Perform procedures or functions as part of the care provided~~
2 ~~by a health care facility, a licensed home health agency, a licensed~~
3 ~~clinic in which there is a physician oversight, a provider who~~
4 ~~contracts with a licensed health care service plan with regard to~~
5 ~~the care or services provided to the enrollees of that health care~~
6 ~~service plan, or a physician, as authorized by Section 4052.2.~~

7 ~~(6) Manufacture, measure, fit to the patient, or sell and repair~~
8 ~~dangerous devices or furnish instructions to the patient or the~~
9 ~~patient's representative concerning the use of those devices.~~

10 ~~(7) Provide consultation to patients and professional information,~~
11 ~~including clinical or pharmacological information, advice, or~~
12 ~~consultation to other health care professionals.~~

13 ~~(8) Furnish emergency contraception drug therapy as authorized~~
14 ~~by Section 4052.3.~~

15 ~~(9) Administer immunizations pursuant to Section 4052.8.~~

16 ~~(b) A pharmacist who is authorized to issue an order to initiate~~
17 ~~or adjust a controlled substance therapy pursuant to this section~~
18 ~~shall personally register with the federal Drug Enforcement~~
19 ~~Administration.~~

20 ~~(c) Nothing in this section shall affect the requirements of~~
21 ~~existing law relating to maintaining the confidentiality of medical~~
22 ~~records.~~

23 ~~(d) Nothing in this section shall affect the requirements of~~
24 ~~existing law relating to the licensing of a health care facility.~~

25 ~~SEC. 3.~~

26 ~~SEC. 2.~~ Section 4052.8 is added to the Business and Professions
27 Code, to read:

28 4052.8. (a) A pharmacist may do either of the following:

29 ~~(1) Administer any immunization pursuant to a protocol with~~
30 ~~a prescriber.~~

31 ~~(2) Administer initiate and administer influenza and~~
32 ~~pneumococcal immunizations, pursuant to standardized protocols~~
33 ~~developed and approved by both the board and the Medical Board~~
34 ~~of California in consultation with public health officers, to any~~
35 ~~person 18 years of age or older. The standardized protocols~~
36 ~~shall be consistent with protocols developed by the Advisory~~
37 ~~Committee on Immunization Practices of the federal Centers for~~
38 ~~Disease Control and Prevention.~~

39 (b) Prior to initiating and administering immunizations, a
40 pharmacist shall complete the American Pharmacists Association's

1 Pharmacy-Based Immunization Delivery Certificate Training
2 Program or another pharmacy-based immunization training
3 certificate program endorsed by the federal Centers for Disease
4 Control and Prevention or the Accreditation Council for
5 Pharmaceutical Education.

6 (c) (1) A pharmacist initiating and administering any
7 immunization pursuant to this section shall also complete three
8 hours of immunization-related continuing education coursework
9 annually.

10 (2) If a pharmacist fails to satisfy this requirement, he or she
11 shall, in addition to any other applicable disciplinary action, retake
12 the training identified in subdivision (b) and also complete the
13 three hours of immunization-related continuing education
14 coursework described in paragraph (1) prior to initiating and
15 administering any further immunizations.

16 (3) The three hours of immunization-related continuing
17 education may be applied toward the continuing education
18 requirement described in Section 4231.

19 (d) A pharmacist initiating and administering any immunization
20 pursuant to this section shall at all times be certified in basic life
21 support.

22 ~~(e) For any patient under 18 years of age, a pharmacist shall~~
23 ~~obtain the consent of a parent or the patient's guardian before~~
24 ~~administration.~~

25 (f)

26 (e) At the time of administration of an immunization, the
27 pharmacist shall do all of the following:

28 (1) Provide the patient or the patient's agent with the appropriate
29 Vaccine Information Statement, produced by the federal Centers
30 for Disease Control and Prevention, for each immunization
31 administered.

32 (2) Provide documentation of administration of the
33 immunization to the patient and the patient's physician or primary
34 care provider, if one can be identified.

35 (3) Provide documentation of administration of the
36 immunization to the appropriate immunization registry.

37 (g)

38 (f) The pharmacist shall maintain an immunization
39 administration record, which shall include, but not be limited to,
40 the name of the vaccine, the expiration date, the date of

1 administration, the manufacturer and lot number, the administration
2 site and route, the Vaccine Information Statement date, and the
3 name and title of the person administering, for the longer of the
4 following periods:

- 5 (1) Ten years from the date of administration.
- 6 (2) If the patient is younger than 18 years of age at the time of
7 administration, three years beyond the patient's 18th birthday. 10
8 years from the date of administration.

9 (h)
10 (g) Any pharmacist initiating and administering vaccines may
11 initiate and administer epinephrine by injection for severe allergic
12 reactions.

13 (i)
14 (h) Any adverse event shall be reported to the Vaccine Adverse
15 Event Reporting System within the United States Department of
16 Health and Human Services.

17 (j)
18 (i) Upon receipt of a vaccine as authorized by this section, a
19 pharmacist is responsible for ~~assuring~~ ensuring that proper vaccine
20 temperatures are maintained during subsequent storage and
21 handling to preserve the potency of the vaccine.

22 (j) The board and the Medical Board of California shall evaluate
23 the effectiveness of the initiation and administration of
24 immunizations pursuant to this section, and report to the
25 appropriate policy committees of the Legislature by January 1,
26 2014.

27 (k) This section shall remain in effect only until January 1, 2015,
28 and as of that date is repealed, unless a later enacted statute, that
29 is enacted before January 1, 2015, deletes or extends that date.

30 SEC. 4. No reimbursement is required by this act pursuant to
31 Section 6 of Article XIII B of the California Constitution because
32 the only costs that may be incurred by a local agency or school
33 district will be incurred because this act creates a new crime or
34 infraction, eliminates a crime or infraction, or changes the penalty
35 for a crime or infraction, within the meaning of Section 17556 of
36 the Government Code, or changes the definition of a crime within
37 the meaning of Section 6 of Article XIII B of the California
38 Constitution.

- 1
- 2 CORRECTIONS:
- 3 Title—Page 1.
- 4 Text—Page 4.
- 5

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Attachment B-1

*AB 1370 (Solorio)
Centralized Hospital Drug Distribution
Proposal to Add Article 7.6 Section 4128 to the
Business and Professions Code*

Letter(s) of Support

AMENDED IN ASSEMBLY JANUARY 4, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1370

Introduced by Assembly Member Solorio

February 27, 2009

~~An act to amend Section 111385 of the Health and Safety Code, relating to public health. An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 1370, as amended, Solorio. ~~Drugs and devices: labeling: expiration date: best before date. Centralized hospital packaging pharmacies.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. A knowing violation of the Pharmacy Law is a crime.

This bill would authorize a centralized hospital packaging pharmacy, as defined, to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care

hospital and one or more general acute care hospitals if the hospitals are under common ownership. The bill would prohibit a person from conducting a centralized hospital packaging pharmacy without a specialty license from the board and would require applicants to apply annually to the board on forms developed by the board. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that the expiration date for drugs prepared in advance of receipt of a patient specific prescription shall not exceed 72 hours, that medications be barcoded to be readable at the inpatient's bedside, and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

~~Existing law, the Sherman Food, Drug, and Cosmetic Law, requires the State Department of Public Health to regulate manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.~~

~~Existing law classifies a drug or device as misbranded if the department determines that the drug or device is liable to deterioration and the drug or device is not packaged and labeled in a form and manner and set forth in regulations of the department.~~

~~This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device. By expanding the definition of an existing crime, this bill would impose a state-mandated local program.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~no~~-yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4029 of the Business and Professions
2 Code is amended to read:

3 4029. (a) "Hospital pharmacy" means and includes a
4 pharmacy, licensed by the board, located within any licensed
5 hospital, institution, or establishment that maintains and operates
6 organized facilities for the diagnosis, care, and treatment of human
7 illnesses to which persons may be admitted for overnight stay and
8 that meets all of the requirements of this chapter and the rules and
9 regulations of the board.

10 (b) A hospital pharmacy also includes a pharmacy that may be
11 located outside of the hospital, in another physical plant that is
12 regulated under a hospital's consolidated license issued pursuant
13 to Section 1250.8 of the Health and Safety Code. As a condition
14 of licensure by the board, the pharmacy in another physical plant
15 shall provide pharmaceutical services only to registered hospital
16 patients who are on the premises of the same physical plant in
17 which the pharmacy is located, *except as provided in Article 7.6*
18 *(commencing with Section 4128)*. The pharmacy services provided
19 shall be directly related to the services or treatment plan
20 administered in the physical plant. Nothing in this ~~paragraph~~
21 *subdivision* shall be construed to restrict or expand the services
22 that a hospital pharmacy may provide.

23 SEC. 2. Article 7.6 (commencing with Section 4128) is added
24 to Chapter 9 of Division 2 of the Business and Professions Code,
25 to read:

26
27 Article 7.6. Centralized Hospital Packaging Pharmacies
28

29 4128. (a) Notwithstanding Section 4029, a centralized hospital
30 packaging pharmacy may prepare medications, by performing the
31 following specialized functions, for administration only to
32 inpatients within its own general acute care hospital and one or

1 *more general acute care hospital if the hospitals are under common*
2 *ownership.*

3 *(1) Preparing unit dose packages for single administration to*
4 *inpatients from bulk containers, if each unit dose package is*
5 *barcoded to contain at least the information required by Section*
6 *4128.4.*

7 *(2) Preparing compounded unit dose drugs for parenteral*
8 *therapy for administration to inpatients, if each compounded unit*
9 *dose drug is barcoded to contain at least the information required*
10 *by Section 4128.4.*

11 *(3) Preparing compounded unit dose drugs for administration*
12 *to inpatients, if each unit dose package is barcoded to contain at*
13 *least the information required by Section 4128.4.*

14 *(b) For the purposes of this article, a "centralized hospital*
15 *packaging pharmacy" means a licensed hospital pharmacy located*
16 *within a general acute care hospital, as defined in subdivision (a)*
17 *of Section 1250 of the Health and Safety Code.*

18 *4128.1. (a) No person shall conduct a centralized hospital*
19 *packaging pharmacy unless it has obtained a specialty license*
20 *from the board.*

21 *(b) A licensed hospital pharmacy serving only its own inpatients*
22 *shall not be required to obtain a specialty license as described in*
23 *subdivision (a).*

24 *4128.2. (a) In addition to the pharmacy license requirement*
25 *described in Section 4110, a centralized hospital packaging*
26 *pharmacy shall obtain a specialty license from the board prior to*
27 *engaging in the functions described in Section 4128.*

28 *(b) An applicant seeking a specialty license pursuant to this*
29 *article shall apply to the board on forms established by the board.*

30 *(c) Before issuing the specialty license, the board shall inspect*
31 *the pharmacy and ensure that the pharmacy is in compliance with*
32 *this article and regulations established by the board.*

33 *(d) A license to perform the functions described in Section 4128*
34 *may only be issued to a pharmacy that is licensed by the board as*
35 *a hospital pharmacy.*

36 *(e) A license issued pursuant to this article shall be renewed*
37 *annually and is not transferrable.*

38 *(f) An applicant seeking renewal of a specialty license shall*
39 *apply to the board on forms established by the board.*

1 (g) A license to perform the functions described in Section 4128
2 shall not be renewed until the pharmacy has been inspected by the
3 board and found to be in compliance with this article and
4 regulations established by the board.

5 (h) The fee for issuance or annual renewal of a centralized
6 hospital packaging pharmacy license shall be six hundred dollars
7 (\$600) and may be increased by the board to eight hundred dollars
8 (\$800).

9 4128.3. A centralized hospital packaging pharmacy may
10 prepare and store a limited quantity of the unit dose drugs
11 authorized by Section 4128 in advance of receipt of a patient
12 specific prescription in a quantity as is necessary to ensure
13 continuity of care for an identified population of inpatients of the
14 general acute care hospital based on a documented history of
15 prescriptions for that patient population. The expiration date for
16 these drugs shall not exceed 72 hours.

17 4128.4. Any unit dose medication produced by a centralized
18 hospital packaging pharmacy shall be barcoded to be readable at
19 the inpatient's bedside. A reading of the barcode shall display all
20 of the following:

- 21 (a) The date the medication was prepared.
- 22 (b) The components used in the drug product.
- 23 (c) The lot number or control number.
- 24 (d) The National Drug Code Directory number.
- 25 (e) The name of the centralized hospital packaging pharmacy.

26 4128.5. The label for each unit dose medication produced by
27 a centralized hospital packaging pharmacy shall contain all of the
28 following:

- 29 (a) The expiration date.
- 30 (b) The established name of the drug.
- 31 (c) The quantity of the active ingredient.
- 32 (d) Special storage or handling requirements.

33 4128.6. All compounding and packaging functions specified
34 in Section 4128 shall be performed only in the licensed centralized
35 hospital packaging pharmacy and that pharmacy shall comply
36 with all applicable regulations, including, but not limited to,
37 regulations regarding compounding and when appropriate, sterile
38 injectable compounding.

39 4128.7. A centralized hospital packaging pharmacy and the
40 pharmacists working in the pharmacy shall be responsible for the

1 integrity, potency, quality, and labeled strength of any unit dose
2 drug product prepared by the centralized hospital packaging
3 pharmacy.

4 SEC. 3. No reimbursement is required by this act pursuant to
5 Section 6 of Article XIII B of the California Constitution because
6 the only costs that may be incurred by a local agency or school
7 district will be incurred because this act creates a new crime or
8 infraction, eliminates a crime or infraction, or changes the penalty
9 for a crime or infraction, within the meaning of Section 17556 of
10 the Government Code, or changes the definition of a crime within
11 the meaning of Section 6 of Article XIII B of the California
12 Constitution.

13 SECTION 1. Section 111385 of the Health and Safety Code
14 is amended to read:

15 ~~111385. Any drug or device is misbranded if the department
16 determines that the drug or device is liable to deterioration, unless
17 it is packaged in that form and manner and its label bears a
18 statement of the precautions, as the department, by regulation, may
19 require as necessary for the protection of public health, including,
20 but not limited to, "best before" date in addition to the expiration
21 date of the effectiveness of the drug or device. The regulations
22 shall not be established for any drug or device recognized in an
23 official compendium, unless the department has informed the
24 appropriate body, charged with the revision of the official
25 compendium, of the need for that packaging or labeling
26 requirements and that body has not prescribed the requirements
27 in a reasonable length of time.~~

28 SEC. 2. No reimbursement is required by this act pursuant to
29 Section 6 of Article XIII B of the California Constitution because
30 the only costs that may be incurred by a local agency or school
31 district will be incurred because this act creates a new crime or
32 infraction, eliminates a crime or infraction, or changes the penalty
33 for a crime or infraction, within the meaning of Section 17556 of
34 the Government Code, or changes the definition of a crime within
35 the meaning of Section 6 of Article XIII B of the California
36 Constitution.

O

January 12, 2010

The Honorable Mary Hayashi, Chair
Assembly Business and Professions Committee
State Capitol, PO Box 942849
Sacramento, CA 94249-0018

RE: AB 1370 (Solorio)
Position: **SUPPORT IF AMENDED**

Dear Assemblymember Hayashi:

The California Society of Health-System Pharmacists (CSHP) has proudly adopted a position of **Support if Amended** on **AB 1370 (Solorio)** as amended on January 4, 2009 with guidance from the California State Board of Pharmacy. CSHP believes that this bill will enhance patient safety in acute care hospitals by allowing centralized compounding and packaging providing a more affordable option for Bed Side Point of Care (administration of medications following barcode verification) and more focus on product preparation and packaging as the primary job function.

In addition, being able to centralize compounding and packaging needs within a healthcare system will enable the use of high speed, accurate, automated equipment with less capital costs. This will allow many more sites to improve the safety of drug distribution and move forward with Bed Side Point of Care to reduce medication errors. Without the efficiencies of centralized operations, this may be cost prohibitive.

CSHP plans to further work with the sponsors of AB 1370, the California Board of Pharmacy, to modify the expiration dating designated at 72-hours found in 4128.3 as expiration dating varies by product (UD, IV, topical) and is already fully regulated by federal and state agencies. Once again, **CSHP urges your "Aye" vote on AB 1370** with the condition that the expiration dating period of 72-hours be eliminated.

Founded in 1962, CSHP represents over 4,000 pharmacists, pharmacy students, pharmacy technicians, and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings, including, but not limited to, hospitals, integrated healthcare systems, clinics, home healthcare and ambulatory care settings.

If we can be of any further assistance, please do not hesitate to contact CSHP Legislative Advocate Bryce W.A. Docherty at (916) 446-4343 or me at (916) 447-1033.

Respectfully,



Dawn Benton
Executive Vice President/CEO

cc: The Honorable Jose Solorio
Members of the Assembly Business and Professions Committee
Ross Warren, Consultant, Assembly Business and Professions Committee
Ted Blanchard, Consultant, Assembly Republican Caucus

Attachment B-2

Reverse Distributors

*Proposal to Amend
Business and Professions Code
§4040.5, §4081 and §4126.5*

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned by the patient or the patient's agent to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient or a patient's agent to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler as defined in Health and Safety Code section (insert number here).

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

- 4126.5.** (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
 - (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
 - (3) A licensed wholesaler acting as a reverse distributor.
 - (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
 - (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
 - (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
 - (7) To another pharmacy under common control.
 - (8) A licensed integrated waste hauler, as defined in Health and Safety Code section (insert section number), for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy.**
 - (9) Add language dealing with the return of drugs to pharmacy by consumers when Class I recall ordered by FDA. (Not sure what language we would need here; let's discuss further.)**

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all drugs returned to a wholesaler or provided to a reverse distributor shall document the quantity or weight of the drugs returned, the date the drugs were returned and the names of the reverse distributors or wholesalers entity to whom the drugs were provided. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the

date and name of the licensed **integrated** waste hauler. For the purpose of this section, "licensed integrated waste hauler" means a person or entity as defined in Health and Safety Code section (insert number here).

Attachment B-3

Omnibus Proposal #1

*Proposal to
Amend Business and Professions Code §4196(e)
and
Add Business and Professions Code §4200.1 and
§4362*

California State Board of Pharmacy
2010 – Omnibus Proposal #1
Senate Committee on Business, Professions & Economic Development

**§ 4196. License Required: Temporary License on Transfer of Ownership;
Persons Authorized in Storage Area**

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying

information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

§ 4200.1 Retaking Examinations; Limits; Requirements

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

§ 4362. Entry into the Pharmacists Recovery Program

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

- (1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.
- (2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of \$125 monthly to cover a portion of the administrative costs borne by the board to contract for these

services. This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

Attachment B-4

Omnibus Proposal #2

*Proposal to
Amend Various Sections of the
Business and Professions Code
To Update References To The Following:*

*California Department of Public Health
Department of Health Care Services
Physical Therapy Board of California*

**California State Board of Pharmacy
2010 – Omnibus Proposal #2
Senate Committee on Business, Professions & Economic Development**

4017. Authorized Officers of the Law

4017. "Authorized officers of the law" means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State California Department of Public Health Services, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

4027. Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

4027. (a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in paragraph (4) of subdivision (a) of Section 4052, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in paragraph (5) of subdivision (a) of Section 4052, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State California Department of Public Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

4028. Licensed Hospital

4028. "Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and includes any institution classified under regulations issued by the State California Department of Public Health Services as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

4037. Pharmacy

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State California Department of Public Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

4052.3 Emergency Contraception Drug Therapy; Requirements and Limitations

4052.3. (a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are

reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State California Department of Public Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

4059. (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State California Department of Public Health Services. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy **Board** ~~Examining Committee~~ of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

4072. Oral or Electronic Transmission of Prescription – Health Care Facility

4072. (a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the State Department of Public Health Services in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

4119. (a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State California Department of Public Health Services set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

4127.1 License to Compound Injectable Sterile Drug Products Required

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may

not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State California Department of Public Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4169. Prohibited Acts

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State California Department of Public Health Services.

~~(e) This section shall become operative on January 1, 2008.~~

4181 License Requirements; Policies and Procedures; Who May Dispense

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State California Department of Public Health Services relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4191. Compliance with California Department of Public Health Requirements; Who May Dispense Drugs

4191. (a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State California Department of Public Health Services and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4425. Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring

4425. (a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

4426. Requirement to Study Reimbursement Rates

4426. The State Department of Health Care Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

Attachment C-2

*Proposal to Amend Business and Professions Code
§4081, §4104 and §4112
For Inclusion In
DCA's Enforcement Model*

§4081

Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) When requested by an inspector or authorized representative of the board, the owner, corporate officers, or manager of any entity licensed by the board shall provide the board with records as requested within 72 hours of the request. The entity may request an extension of this timeframe for a period up to 14 days. Such a request must be made in writing and is subject to approval.

~~(b) (c)~~ The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

~~(e) (d)~~ The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

~~(d) This section shall become operative on January 1, 2006.~~

§4104

Licensed Employee, Theft or Impairment: Pharmacy Procedures

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

§4112

Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.

~~(d)~~ (e) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

~~(e)~~ (f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

~~(f)~~ (g) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~ (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~ (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~ (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.



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

Legislation and Regulation Committee

Greg Lippe, Public Member, Chair
Ryan Brooks, Public Member
Stan Weisser, RPh
Shirley Wheat, Public Member

REGULATION REPORT AND ACTION

A. DISCUSSION AND POSSIBLE ACTION

Board Action to Adopt Amendments to Title 16 CCR 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination; Confidentiality

ATTACHMENT A

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

The formal rulemaking was noticed on October 30, 2009. The 45-day comment period concluded on December 14, 2009, and the board did not receive any comments to the proposed rulemaking. A copy of the board-approved language is attached.

B. FOR INFORMATION. Board Adopted Regulations – Approved by the Office of Administrative Law

ATTACHMENT B

Repeal Title 16 CCR Sections 1716.1 and 1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 1735 through 1735.8 – Pharmacies that Compound

Current pharmacy law authorizes a pharmacist to compound drug products as well as compound injectable sterile drug products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that

compound sterile injectable products. There were no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. The proposal established guidelines to provide uniformity in compounding for California consumers. The rulemaking incorporates by reference Form 17M-39, Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment (Rev. 01/10).

Draft regulatory text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

At its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. The modified text was noticed on February 26, 2009.

At the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. The board again considered modifications to proposed section 1735.3(a)(6) and subsequently voted to pursue a 2nd 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within 24 hours, as specified. The 2nd 15-day comment period was noticed on May 4, 2009.

At the July 2009 Board Meeting, the board considered the comments received during the 2nd 15-day comment period, as well as a draft response to each comment. The board then voted to approve the subcommittee's recommendation to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the Office of Administrative Law to allow for implementation. The board further moved that staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

After staff compiled the final regulatory proposal, the department reviewed and approved the rulemaking which was transmitted to the Office of Administrative Law on November 19, 2009. OAL approved the rulemaking on January 6, 2010. As specified by the board, the rulemaking has an effective date six months following OAL approval: July 6, 2010. As directed by the board, staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

A copy of the Adopted Text and Self-Assessment Form are attached.

C. FOR INFORMATION. Board Approved Regulations – Currently Noticed

Proposed Rulemaking to Add Title 16 Section 1707.2 to the California Code of Regulations – Fingerprint Requirements

ATTACHMENT C

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic

fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concludes February 15, 2010.

A copy of the proposed regulatory language is attached.

D. FOR ACTION. Board Action to Initiate Rulemaking

Discussion and Possible Action to Amend Title 16 CCR Section 1746 – Emergency Contraception Protocol

ATTACHMENT D

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004.

Staff recommends that an error be corrected in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." The heading should designate micrograms – not milligrams. While the board deems this to be a typographical error, the regulation (as originally adopted) specified milligrams, not micrograms. As a result, a formal regulation proposal is required to correct this heading. A copy of the current regulation with proposed amendments is attached.

E. FOR INFORMATION. Board Approved Regulations – Awaiting Notice

1. Proposed Addition to Title 16 CCR Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

ATTACHMENT E-1

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff does not anticipate proceeding with this regulation

change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

A copy of the approved text is attached.

2. Proposed Addition of Title 16 CCR §1751.xx – Accreditation Agencies for Pharmacies That Compound Injectable Sterile Drug Products

ATTACHMENT E-2

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

A copy of the approved text is attached.

F. FOR INFORMATION. Regulations Under Development

1. Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. This subcommittee has not held any meetings. Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.

2. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR §1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR §1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR §1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting and in advance of the April 2010 Board Meeting.

3. Development of Enforcement Component of Security of Emergency Kits

ATTACHMENT F-3

AB 931 amended section 1261.5 of the Health and Safety Code to increase the number of oral dosage form and suppository dosage form drugs from 24 to 48 for storage within an emergency supplies container, as defined in Section 4119 of the Business and Professions Code. These "E-kits" are within the jurisdiction of the California Department of Public Health (CDPH), and the measure specifies that CDPH may limit the number of any doses of each drug available to not more than 16 doses of any separate drug dosage form. The bill

was signed by the Governor and Chapter 491 Statutes 2009 was filed with the Secretary of State on that date. The provisions of AB 931 became effective on January 1, 2010. A copy of the bill is attached.

Attachment A

*Proposed Amendment to
16 CCR §1721 and §1723.1
Dishonest Conduct on a Pharmacist Licensure
Examination; Confidentiality*

Order of Adoption
Board of Pharmacy
California Code of Regulations

**To Amend Division 17 of Title 16 CCR §1721 and
To Amend Division 17 of Title 16 CCR §1723.1**

Dishonest Conduct During Examination and Confidentiality of Examination Questions

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern card and license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

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

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

Virginia Herold
Executive Officer

Date

Attachment B

Approved Text

*Amendments to 16 CCR §1751 - §1751.8 and
Addition of 16 CCR §1735 - §1735.8
Pharmacies that Compound*

Form 17M-39

*Community Pharmacy & Hospital Outpatient
Pharmacy Self Assessment*

Order of Adoption
Board of Pharmacy
California Code of Regulations

**To Repeal Division 17 of Title 16 CCR §1716.1 and §1716.2 and
To Adopt Division 17 of Title 16 CCR §1735 and §1735.1 – §1735.8, and
To Amend Division 17 of Title 16 CCR §1751 and §1751.1 -- §1751.8
Requirements for Compounding and Sterile Injectable Compounding**

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

- ~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~
- ~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~
 - ~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~
 - ~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~
- ~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~
- ~~(c) "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.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.2. Record Requirements--Compounding for Future Furnishing.

~~(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:~~

- ~~(1) The date of preparation.~~
- ~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If~~

~~the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

~~(8) The package size and the number of units prepared.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

Article 4.5. Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies.

- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
- (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions.

- (a) "Integrity" means retention of potency until the expiration date noted on the label.
- (b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.
- (c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) "Strength" means amount of active ingredient per unit of a compounded drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements.

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with

pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
- (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post-compounding process or procedures required, if any.
 - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 01/10.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the

issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products.

- (a) For each compounded drug product, the pharmacy records shall include:
- (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.
 - (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products.

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures.

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

- (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment.

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff.

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance.

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
- (b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12₂ of Title 24, ~~Part 4,~~ Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance ~~in~~ with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, ~~Chapter 4A~~ of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§~~1751.3~~, 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~4746.4~~ 1735.2 shall, in addition to those records required by section ~~4746.2~~ 1735.3, ~~have~~ make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.

- (3) Certification of the sterile compounding environment.
- (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
- (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
- (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

~~In addition to existing labeling requirements to the labeling information required under Business and Professions Code section 4076 and section 1735.4,~~ a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy

and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

- (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- (J) Sterilization.
- (K) End-product evaluation and testing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.04. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944 Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.1. Laminar Flow Biological Safety Cabinet.

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. Recordkeeping Requirements.

- ~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1-1735.2 shall, in addition to those records required by section 1716.2-1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~
- ~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~
- ~~(1) The training and competency evaluation of employees in sterile product procedures.~~
 - ~~(2) Refrigerator and freezer temperatures.~~
 - ~~(3) Certification of the sterile compounding environment.~~
 - ~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
 - ~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
 - ~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~
- ~~(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5. 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

- (A) Aseptic technique.
- (B) Pharmaceutical calculations and terminology.
- (C) Sterile product compounding documentation.
- (D) Quality assurance procedures.
- (E) Aseptic preparation procedures.
- (F) Proper gowning and gloving technique.
- (G) General conduct in the controlled area.
- (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- (I) Sterilization techniques.
- (J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

Note: Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be~~ a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.
- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Virginia Herold
Executive Officer

Date



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

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug product 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 completed 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 & Hospital Outpatient Pharmacy Compounding 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: _____

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

- 2. _____ RPH # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
- 6. _____ RPH # _____ Exp. Date: _____
- 7. _____ INT # _____ Exp. Date: _____
- 8. _____ INT # _____ Exp. Date: _____
- 9. _____ INT # _____ Exp. Date: _____
- 10. _____ TCH # _____ Exp. Date: _____
- 11. _____ TCH # _____ Exp. Date: _____
- 12. _____ TCH # _____ Exp. Date: _____
- 13. _____ TCH # _____ Exp. Date: _____
- 14. _____ TCH # _____ Exp. Date: _____
- 15. _____ TCH # _____ Exp. Date: _____
- 16. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

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.

COMPOUNDING

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

The pharmacy compounds prescriptions as defined in CCR 1735.

The compounding pharmacist understands the definitions of integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined. (CCR 1735.2[b])

The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements (CCR 1735.2[d][1-6]):

Active ingredients used.

Inactive ingredients used.

Process and/or procedure used to prepare the drug.

Quality reviews required at each step in the preparation of the drug.

Post-compounding process or procedures if required.

Expiration dating requirements.

The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])

All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])

Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The "beyond use date" of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

A record for each compounded drug product includes the following (CCR 1735.3[a][1-10]):

The master formula record.

The date the drug product was compounded.

The identity of the pharmacy personnel who compounded the drug product.

The identity of the pharmacist reviewing the final drug product.

The quantity of each component used in compounding the drug product.

The manufacturer or supplier and lot number of each component. Exempt from this requirement are sterile drug products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

The equipment used in compounding the drug product.

The pharmacy assigned reference or lot number for the compounded drug product.

The expiration date of the final compounded drug product.

The quantity or amount of drug product compounded.

- The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])
- Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])
- The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])
- The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

- The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])
- The prescription label contains all the information required in B&PC 4076. (CCR 1735.4[a])
- The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])
- Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date. (CCR 1735.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

- The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]):
- Procurement procedures.
- Methodologies for the formulation and compounding of drugs.

Facilities and equipment cleaning, maintenance and operations.

Other standard operating procedures related to compounding.

- The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])
- The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])
- The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2])
- The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[c][3])
- The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[c][4])
- The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[c][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

- The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- All equipment used to compound drug products is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
- Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

The pharmacy's quality assurance plan includes the written procedures and standards for the following:

Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[c])

Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

COMPOUNDING STERILE INJECTABLE DRUGS

FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS

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 _____

9. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

The contractual arrangement is reported to the board within 30 days of commencing that compounding.

10. Sterile Injectable Compounding; Compounding Area (CCR 1751)

Yes No N/A

If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. 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])

The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)

The laminar airflow hoods and clean room are certified annually; (CCR 1751)

Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)

A sink with hot and cold running water; (CCR 1751)

A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

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 and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

In addition to the labeling information required under Business and Professions Code section 4076 and 16 CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])

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 that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and, in addition to the elements required by section 1735.5, includes: (CCR 1751.2[a][1-7])

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 1751.3[b])

Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])

Policies and procedures address the following: (CCR 1751.3 [d][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 (e.g., 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: _____

14. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])

Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])

All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])

The preparation of parenteral cytotoxic agents is done in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations and includes: (CCR 1751.4[e])

A laminar airflow hood, which is certified annually.

Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.5[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[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 1751.5[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

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 1751.6[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 1751.6[b])

Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])

The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])

When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[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 1751.6[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Aseptic preparation 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 1751.6[e][2])

Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])

Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])

Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

There is a written, documented, ongoing quality assurance program maintained by the pharmacy 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][1-4])

Cleaning and sanitization of the parenteral medication preparation area;

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

Actions 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 1735.2[h]).

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 microbial 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 whenever aseptic techniques are observed. (CCR 1751.7[b])

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. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

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 _____
(Pharmacist-in-Charge)

Date _____

Attachment C

*Proposed Text to
Add §1707.2 to Title 16 CCR*

Pharmacist Fingerprint Requirements

Title 16. Board of Pharmacy Proposed Language

To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after ([OAL insert effective date]).

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

Attachment D

*Draft Regulatory Text to Amend
16 CCR §1746
Emergency Contraception Protocol*

**Title 16. Board of Pharmacy
Proposed Language**

To Amend Section 1746 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§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).

(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits 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 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.

(4) 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 medication record 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 4052b(3).

(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 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.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile 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) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception

<i>Dedicated Emergency Contraception</i>				
Brand	Manufacturer	Tablets per Dose	EthinylEstradiol per Dose (mg mcg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Duramed	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Duramed	1 tablet per dose	0	0.75
Preven	Duramed	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg mcg)	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

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

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</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 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

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.3, Business and Professions Code.

Attachment E-1

*Board-Approved Text to Add
16 CCR §1785
Self-Assessment of a Veterinary Food-Animal
Drug Retailer*

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler'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 designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

Attachment E-2

Board-Approved Text to Add

16 CCR §1751.xx

*Accreditation Agencies for Pharmacies that
Compound Injectable Sterile Drug Products*

Board of Pharmacy
Specific Language to Add Section 1751.xx

Add Section 1751.xx to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.xx – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1 or section 4127.2 shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standards-setting organizations.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.

(4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Attachment F-3

*AB 931 (Fletcher)
Emergency Supply Kits*

Assembly Bill No. 931

CHAPTER 491

An act to amend Section 1261.5 of the Health and Safety Code, relating to health facilities.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 931, Fletcher. Emergency supplies.

Existing law provides for the licensing and regulation by the State Department of Public Health of health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities.

Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy and establishes requirements for the dispensing of drugs.

Existing law authorizes a pharmacy to furnish dangerous drugs or devices to a licensed health facility for storage in a secure emergency pharmaceutical supplies container that is maintained within the facility under regulations of the department. Existing law limits the number of oral dosage form and suppository dosage form drugs for storage within this container to 24. It also authorizes the department to limit the number of doses of each drug available to a skilled nursing facility or intermediate care facility to not more than 4 doses of any separate drug dosage form in each emergency supply.

This bill would increase the storage container limit to 48, as specified. The bill would also increase the authorized dosage amount available to a skilled nursing facility or intermediate care facility.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and Professions Code, shall be limited to 48. The State Department of Public Health may limit the number of doses of each drug available to not more than 16 doses of any separate drug dosage form in each emergency supply.

(b) Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be

psychotherapeutic drugs, except that the department may grant a program flexibility request to the facility to increase the number of psychotherapeutic drugs in the emergency supplies container to not more than 10 if the facility can demonstrate the necessity for an increased number of drugs based on the needs of the patient population at the facility. In addition, the four oral form or suppository form psychotherapeutic drug limit shall not apply to a special treatment program service unit distinct part, as defined in Section 1276.9. The department shall limit the number of doses of psychotherapeutic drugs available to not more than four doses in each emergency supply. Nothing in this section shall alter or diminish informed consent requirements, including, but not limited to, the requirements of Section 1418.9.

(c) Any limitations established pursuant to subdivisions (a) and (b) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

<p>Objective 3.1</p>	<p>Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.</p>
<p>Measure:</p>	<p>100 percent successful enactment of promoted legislative changes.</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date. <ul style="list-style-type: none"> <i>Sept. 30, 2006:</i> Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008. <i>June 2007:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. <i>July 2008:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments. <i>Sept. 2008:</i> Governor signs SB 963 (Chapter 385, Statutes of 2008) <i>Sept. 2009:</i> Sunset extension amended into AB 1071. Bill enrolled and sent to Governor. <i>Oct. 2009:</i> Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013. 2. Sponsor legislation to update pharmacy law. <ul style="list-style-type: none"> <i>Enacted - 1st Qtr. 08/09:</i> SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions <i>Oct. 2007:</i> Board sponsors omnibus provisions for 2008. Four types of changes are discussed. <ol style="list-style-type: none"> (1) Changes specific to the PIC and DRC requirements <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4161 – Nonresident wholesaler • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts (2) Changes to allow for the use of mobile pharmacies <ul style="list-style-type: none"> • Section 4062 – Furnishing Dangerous Drugs During an Emergency. • Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership. (3) General changes <ul style="list-style-type: none"> • Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions. • Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory • Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy. • Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee. • H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

Jan. 2008: *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.*

Board approved language for omnibus bill.

April 2008: *Some provisions of omnibus bill removed:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

Oct. 2008: *Governor vetoes SB 1779*

1st Qtr. 08/09: *Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change:*

(1) Changes specific to the PIC and DRC requirements

- *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*
- *Section 4036.5 – Pharmacist-in-Charge*
- *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*
- *Section 4329 – Nonpharmacists; Prohibited Acts*
- *Section 4330 – Proprietors; Prohibited Acts*

(2) Changes to allow for the use of mobile pharmacies

- *Section 4062 – Furnishing Dangerous Drugs During an Emergency.*
- *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.*

(3) *General changes*

- *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.*
- *Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*
- *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*
- *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*
H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
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- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

1st Qtr. 08/09: Board seeks to introduce additional changes:

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

New Provisions

- *4200.1 – Pharmacist Examination; Remedial Education*
- *4112 – Non-resident Pharmacy; Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

2nd Qtr. 08/09: Provisions contained in SB 821:

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*

- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*

New Provisions

- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

3rd Qtr. 08/09: *Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.*

Jan 2010: *Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.*

Omnibus Proposal #1:

- (1) *Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)*
 - * *§650.1 – Lease Prohibition – Hospitals or Prescribers*
 - * *§652 – Violation of Unprofessional Conduct*
 - * *§4017 – Authorized Officers of the Law*
 - * *§4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
 - * *§4028 – Definition of Licensed Hospital*
 - * *§4037 – Definition of Pharmacy*
 - * *§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations*
 - * *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions.*
 - * *§4072 – Oral or Electronic Transmission of Prescription – Health Care Facility*
 - * *§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies*
 - * *§4127.1 – License to Compound Injectable Sterile Drug Products Required*
 - * *§4169 – Prohibited Acts (also, strike operative date of 2008)*
 - * *§4181 – License Requirements; Policies and Procedures; Who May Dispense*
 - * *§4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs*
- (2) *Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)*
 - * *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions*
- (3) *Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)*

- * §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
- * §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.

Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12)

Oct 2009: Board approves regulatory language for Initial Notice.

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.

Sept. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

*Oct. 2007: Governor signs the following:
 AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.
 SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*

	<p>SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal. Governor vetoes the following: AB 249 (Eng) Healing Arts: Settlement Agreements. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure. AB 1025 (Bass) Professions and Vocations: Denial of Licensure. SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</p> <p>Oct. 2008: Governor signs the following: AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review Governor vetoes the following: AB 501 (Swanson) Pharmaceutical Devices AB 865 (Davis) State Agencies AB1574 (Plescia) Surgical Clinics: Licensure</p> <p>Jan. 2009: Legislation introduced affecting Pharmacy law: (New Session) AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections. SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</p> <p>April 2009: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD) AB 1370 (Solorio) "Best Before" Date on a Prescription Label AB 1458 (Davis) Drugs: Adverse Effects Reporting SB 26 (Simitian) Home-Generated Pharmaceutical Waste SB 43 (Alquist) Cultural and Linguistic Competency SB 238 (Calderon) Medical Information SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs</p>
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	<p><i>SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus</i></p> <p><i>SB 484 (Wright) Ephedrine Products to Schedule V</i></p> <p><i>SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews</i></p> <p><i>SB 762 (Aanestad) Professions and Vocations; Healing Arts</i></p> <p>June 2009: <i>AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012</i></p> <p><i>AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid</i></p> <p><i>AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container</i></p> <p><i>AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)</i></p> <p><i>SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus</i></p> <p><i>SB 484 (Wright) Ephedrine Products to Schedule V</i></p> <p><i>SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews</i></p> <p><i>SB 762 (Aanestad) Professions and Vocations; Healing Arts</i></p> <p>July 2009: <i>Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts</i></p> <p>Oct. 2009: <i>Governor signs SB 819 (Omnibus)</i></p> <p><i>Governor signs SB 821 (Omnibus)</i></p> <p><i>Governor signs SB 470 (Corbett) - "Purpose"</i></p> <p><i>Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset</i></p> <p><i>Governor signs AB 931 (Fletcher) - Emergency Supplies Container</i></p> <p><i>Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia</i></p>
7.	<p>Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</p> <p>March 2007: <i>Licensing Committee considers and approves concept. More work is required.</i></p> <p>June 2007: <i>Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.</i></p> <p>Sept. 2007: <i>Licensing Committee forwards to full board legislative proposal.</i></p> <p>Oct. 2007: <i>Board approved draft legislation.</i></p> <p>Nov. 2007: <i>Staff meeting with stakeholders to elicit support for the proposal.</i></p> <p>Dec. 2007: <i>Staff develop fact sheets and work with experts in immunizations.</i></p> <p>Feb. 2009: <i>Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.</i></p> <p>April 2009: <i>Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.</i></p> <p>May 2009: <i>Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)</i></p> <p>Jan 2010: <i>Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.</i></p> <p>Jan 2010: <i>AB 977 passes out of Assembly Health Committee</i></p>

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.
- Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
- Apr. 2008: First public forum held in Fremont.
- May 2008: Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.
- June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.
- July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.
- Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.
Public Education Committee updated on the status of survey results.
- Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.
- May 2009: Bill passes out of the Senate
- Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).
- Oct 2009: Board approves regulatory language for notice.
- Nov 2009: Regulatory effort initiated (See Objective 3.2, Task 16)
9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.
- Dec. 2008: Board receives findings of independent fee audit.
- Jan. 2009: Board votes to pursue fee increase.
- Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.
- June 2009: Bill passes out of the Assembly.
- Sept. 2009: Bill is enrolled and sent to the Governor.
- Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.
- Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)
- Jan 2010: Statutory fee schedule implemented (supercedes 16 CCR 1749)
10. Advocate legislation to enhance the board's enforcement activities.
- Jan 2010: Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):
Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory,
Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> 3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Aug. 2006: Final changes to Disciplinary Guidelines being compiled by staff.</i> <i>Dec. 2006: Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.</i> <i>June 2007: Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.</i> <i>Sept. 2007: Enforcement Committee approves Disciplinary Guidelines and recommends board approval.</i> <i>Oct. 2007: Board approves Disciplinary Guidelines for 45-day comment period.</i> <i>Feb. 2008: Regulation released for 45 days of public comment.</i> <i>April 2008: Board adopts regulation.</i> <i>Sept. 2008: Rulemaking file submitted for review by the administration.</i> <i>Jan. 2009: Board pursues 15-day comment to eliminate an optional provision contained in the guidelines.</i> <i>March 2009: Rulemaking compiled and resubmitted for review by the administration.</i> <i>May 2009: Regulation takes effect.</i> 6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 7. Exempt the address of records of interns from display on the board's website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i>

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).
- Feb. 2007: Board notices regulation for 45 days comment period.*
- April 2007: Board considers comments submitted during public comment period and modifies text regulation to reflect comments.*
- May 2007: New section 1707.2 released for 45 days of public comment.*
- July 2007: Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.*
- Sept. 2007: File submitted to the Office of Administrative Law for review.*
- Oct. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Regulation changes takes effect.*
- Nov. 2007: Staff solicits design submissions from graphic designers.*
- Jan. 2008: Communication and Public Education Committee make recommendations on design submissions.*
- Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.*
10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.
- Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:*
- 1707 – Waiver of requirements for off-site storage of records*
 - 1709.1 – Designation of pharmacist-in-charge*
 - 1715 – Self-assessment of a pharmacy by the pharmacist-in-charge*
 - 1717 – Pharmacy practice*
 - 1746 – Emergency contraception*
 - 1780.1 – Minimum standards for veterinary food-animal drug retailers*
 - 1781 – Exemption certificate*
 - 1787 – Authorization to distribute dialysis drugs and devices*
 - 1790 – Assembling and packaging*
 - 1793.8 – Technician check technician*
 - Repeal section 1786 – Exemptions*
- March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*
11. Increase fees to keep the board's contingency fund solvent and maintain operations.
- Nov. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.*
- Jan. 1, 2008: New fees take effect.*
- Oct. 2009: Governor signs AB 1071, new fee schedule.*
- Jan 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)*

12. Secure regulatory standards for pharmacies that compound.
- Dec. 2006: Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.*
- March 2007: Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.*
- May 2007: Licensing Committee holds detailed discussion on compounding regulations.*
- Sept. 2007: Licensing Committee forwards regulation proposal to the board for review.*
- Nov. 2007: Board releases language for the 45-day comment period.*
- Jan. 2008: Board held regulation hearing and considers written comments and oral testimony.*
- April 2008: Board votes to withdraw rulemaking.*
- Aug. 2008: Board releases new language for the 45-day comment period.*
- Oct. 2008: Board holds regulation hearing to elicit additional comments.*
- Jan. 2009: Board votes to pursue 15-day notice.*
- April 2009: Board releases second 15-day comment period.*
- May 2009: Board releases second 15-day comment period.*
- July 2009: Board votes to approve regulation.*
- Aug. 2009: Rulemaking submitted for review by the administration.*
- Nov 2009: Rulemaking submitted for review by Office of Administrative Law.*
- Jan 2010: Office of Administrative Law approves regulation.*
13. Establish an ethics course.
- April 2007: Board establishes a subcommittee to examine the development of an ethics course.*
- Oct. 2007: Board votes to pursue regulation change to establish program components.*
- Sept. 2008: Board notices regulation for 45-day comment period.*
- Oct. 2008: Board votes to pursue 15-day comment period and, absent any negative comments, authorizes the Executive Officer to complete the rulemaking file.*
- March 2009: Rulemaking submitted for review by the administration.*
- Aug. 2009: Office of Administrative Law approves regulation.*
- Sept. 2009: Regulation takes effect.*
14. Pharmacist Renewal Requirements
- Dec 2009: Board notices regulation for 45-day comment period.*
15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions
- Oct 2009: Board notices regulation for 45-day comment period.*
- Jan 2010: Board considers adoption of regulation as noticed.*
16. Standardized, Patient-Centered Prescription Labels
- Oct 2009: Board approves language to initiate rulemaking.*
- Nov 2009: Board notices regulation for 45-day comment period.*
- Jan 2010: Regulation hearing scheduled.*
17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC)
- Jan 2010: Board to consider approval of draft regulation to correct a typographical error in the Emergency Contraception Protocol regulation (16 CCR §1746(b)(11)).*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007: Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</i></p> <p><i>Oct. 2007: Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</i></p> <p><i>Jan. 2008: Board approves omnibus language recommended by Legislation and Regulation Committee.</i></p> <ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i> <p><i>April 2008: The following provisions are not incorporated into omnibus bill.</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> <p><i>Sept. 2008: Governor vetoes SB 1779.</i></p> <p><i>Jan. 2009: Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</i></p> <p><i>Sept. 2009: SB 819 and SB 821 enrolled and sent to the Governor.</i></p> <p><i>Oct. 2009: Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</i></p>