

AMENDED IN SENATE APRIL 6, 2016

SENATE BILL

No. 1195

Introduced by Senator Hill

February 18, 2016

An act to amend Sections ~~4800 and 4804.5~~ of 109, 116, 153, 307, 313.1, 2708, 4800, 4804.5, 4825.1, 4830, and 4846.5 of, and to add Sections 4826.3, 4826.5, 4826.7, 4848.1, and 4853.7 to, the Business and Professions Code, and to amend Sections 825, 11346.5, 11349, and 11349.1 of the Government Code, relating to ~~healing arts~~, professional regulation, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1195, as amended, Hill. ~~Veterinary Medical Board: executive officer.~~ *Professions and vocations: board actions: competitive impact.*

(1) Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs, and authorizes those boards to adopt regulations to enforce the laws pertaining to the profession and vocation for which they have jurisdiction. Existing law makes decisions of any board within the department pertaining to setting standards, conducting examinations, passing candidates, and revoking licenses final, except as specified, and provides that those decisions are not subject to review by the Director of Consumer Affairs. Existing law authorizes the director to audit and review certain inquiries and complaints regarding licensees, including the dismissal of a disciplinary case. Existing law requires the director to annually report to the chairpersons of certain committees of the Legislature information regarding findings from any audit, review, or monitoring and evaluation. Existing law authorizes the director to contract for services of experts and consultants where necessary.

Existing law requires regulations, except those pertaining to examinations and qualifications for licensure and fee changes proposed or promulgated by a board within the department, to comply with certain requirements before the regulation or fee change can take effect, including that the director is required to be notified of the rule or regulation and given 30 days to disapprove the regulation. Existing law prohibits a rule or regulation that is disapproved by the director from having any force or effect, unless the director's disapproval is overridden by a unanimous vote of the members of the board, as specified.

This bill would instead authorize the director, upon his or her own initiative, and require the director, upon the request of a consumer or licensee, to review a decision or other action, except as specified, of a board within the department to determine whether it unreasonably restrains trade and to approve, disapprove, or modify the board decision or action, as specified. The bill would require the director to post on the department's Internet Web site his or her final written decision and the reasons for the decision within 90 days from receipt of the request of a consumer or licensee. The bill would, commencing on March 1, 2017, require the director to annually report to the chairs of specified committees of the Legislature information regarding the director's disapprovals, modifications, or findings from any audit, review, or monitoring and evaluation. The bill would authorize the director to seek, designate, employ, or contract for the services of independent antitrust experts for purposes of reviewing board actions for unreasonable restraints on trade. The bill would also require the director to review and approve any regulation promulgated by a board within the department, as specified. The bill would authorize the director to modify any regulation as a condition of approval, and to disapprove a regulation because it would have an impermissible anticompetitive effect. The bill would prohibit any rule or regulation from having any force or effect if the director does not approve the regulation because it has an impermissible anticompetitive effect.

(2) Existing law, until January 1, 2018, provides for the licensure and regulation of registered nurses by the Board of Registered Nursing, which is within the Department of Consumer Affairs, and requires the board to appoint an executive officer who is a nurse currently licensed by the board.

This bill would instead prohibit the executive officer from being a licensee of the board.

~~The~~

(3) *The Veterinary Medicine Practice Act provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board, which is within the Department of Consumer Affairs, and authorizes the board to appoint an executive officer, as specified. Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. That act exempts certain persons from the requirements of the act, including a veterinarian employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties. That act requires all premises where veterinary medicine, dentistry, and surgery is being practiced to register with the board. That act requires all fees collected on behalf of the board to be deposited into the Veterinary Medical Board Contingent Fund, which continuously appropriates fees deposited into the fund. That act makes a violation of any provision of the act punishable as a misdemeanor.*

This bill would extend the operation of the board and the authorization of the board to appoint an executive officer to January 1, 2021. *The bill would authorize a veterinarian and registered veterinary technician who is under the direct supervision of a veterinarian with a current and active license to compound a drug for anesthesia, the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal in a premises currently and actively registered with the board, as specified. The bill would authorize the California State Board of Pharmacy and the board to ensure compliance with these requirements. The bill would instead require veterinarians engaged in the practice of veterinary medicine employed by the University of California or by the Western University of Health Sciences while engaged in the performance of specified duties to be licensed as a veterinarian in the state or hold a university license issued by the board. The bill would require an applicant for a university license to meet certain requirements, including that the applicant passes a specified exam. The bill would also prohibit a premise registration that is not renewed within 5 years after its expiration from being renewed, restored, reissued, or reinstated; however, the bill would authorize a new premise registration to be issued to an applicant if no fact, circumstance, or condition exists that would justify the revocation or suspension of the registration if the registration was issued and if specified fees are paid. By requiring*

additional persons to be licensed and pay certain fees that would go into a continuously appropriated fund, this bill would make an appropriation. By requiring additional persons to be licensed under the act that were previously exempt, this bill would expand the definition of an existing crime and would, therefore, result in a state-mandated local program.

(4) Existing law, except as provided, requires a public entity to pay any judgment or any compromise or settlement of a claim or action against an employee or former employee of the public entity if the employee or former employee requests the public entity to defend him or her against any claim or action against him or her for an injury arising out of an act or omission occurring within the scope of his or her employment as an employee of the public entity, the request is made in writing not less than 10 days before the day of trial, and the employee or former employee reasonably cooperates in good faith in the defense of the claim or action.

This bill would require a public entity to pay a judgment or settlement for treble damage antitrust awards against a member of a regulatory board for an act or omission occurring within the scope of his or her employment as a member of a regulatory board.

(5) The Administrative Procedure Act governs the procedure for the adoption, amendment, or repeal of regulations by state agencies and for the review of those regulatory actions by the Office of Administrative Law. That act requires the review by the office to follow certain standards, including, among others, necessity, as defined. That act requires an agency proposing to adopt, amend, or repeal a regulation to prepare a notice to the public that includes specified information, including reference to the authority under which the regulation is proposed.

This bill would add competitive impact, as defined, as an additional standard for the office to follow when reviewing regulatory actions of a state board on which a controlling number of decisionmakers are active market participants in the market that the board regulates, and requires the office to, among other things, consider whether the anticompetitive effects of the proposed regulation are clearly outweighed by the public policy merits. The bill would authorize the office to designate, employ, or contract for the services of independent antitrust or applicable economic experts when reviewing proposed regulations for competitive impact. The bill would require state boards on which a controlling number of decisionmakers are active market participants

in the market that the board regulates, when preparing the public notice, to additionally include a statement that the agency has evaluated the impact of the regulation on competition and that the effect of the regulation is within a clearly articulated and affirmatively expressed state law or policy.

(6) 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: ~~no~~-yes.

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

1 SECTION 1. Section 109 of the Business and Professions Code
2 is amended to read:

3 ~~109. (a) The decisions of any of the boards comprising the~~
4 ~~department with respect to setting standards, conducting~~
5 ~~examinations, passing candidates, and revoking licenses, are not~~
6 ~~subject to review by the director, but are final within the limits~~
7 ~~provided by this code which are applicable to the particular board,~~
8 ~~except as provided in this section.~~

9 ~~(b)~~

10 109. (a) The director may initiate an investigation of any
11 allegations of misconduct in the preparation, administration, or
12 scoring of an examination which is administered by a board, or in
13 the review of qualifications which are a part of the licensing process
14 of any board. A request for investigation shall be made by the
15 director to the Division of Investigation through the chief of the
16 division or to any law enforcement agency in the jurisdiction where
17 the alleged misconduct occurred.

18 ~~(c)~~

19 (b) (1) The director may intervene in any matter of any board
20 where an investigation by the Division of Investigation discloses
21 probable cause to believe that the conduct or activity of a board,
22 or its members or employees constitutes a violation of criminal
23 law.

24 ~~The~~

1 (2) *The term “intervene,” as used in paragraph (c) of this section*
2 *(1) may include, but is not limited to, an application for a*
3 *restraining order or injunctive relief as specified in Section 123.5,*
4 *or a referral or request for criminal prosecution. For purposes of*
5 *this section, the director shall be deemed to have standing under*
6 *Section 123.5 and shall seek representation of the Attorney*
7 *General, or other appropriate counsel in the event of a conflict in*
8 *pursuing that action.*

9 *(c) The director may, upon his or her own initiative, and shall,*
10 *upon request by a consumer or licensee, review any board decision*
11 *or other action to determine whether it unreasonably restrains*
12 *trade. Such a review shall proceed as follows:*

13 *(1) The director shall assess whether the action or decision*
14 *reflects a clearly articulated and affirmatively expressed state law.*
15 *If the director determines that the action or decision does not*
16 *reflect a clearly articulated and affirmatively expressed state law,*
17 *the director shall disapprove the board action or decision and it*
18 *shall not go into effect.*

19 *(2) If the action or decision is a reflection of clearly articulated*
20 *and affirmatively expressed state law, the director shall assess*
21 *whether the action or decision was the result of the board’s*
22 *exercise of ministerial or discretionary judgment. If the director*
23 *finds no exercise of discretionary judgment, but merely the direct*
24 *application of statutory or constitutional provisions, the director*
25 *shall close the investigation and review of the board action or*
26 *decision.*

27 *(3) If the director concludes under paragraph (2) that the board*
28 *exercised discretionary judgment, the director shall review the*
29 *board action or decision as follows:*

30 *(A) The director shall conduct a full review of the board action*
31 *or decision using all relevant facts, data, market conditions, public*
32 *comment, studies, or other documentary evidence pertaining to*
33 *the market impacted by the board’s action or decision and*
34 *determine whether the anticompetitive effects of the action or*
35 *decision are clearly outweighed by the benefit to the public. The*
36 *director may seek, designate, employ, or contract for the services*
37 *of independent antitrust or economic experts pursuant to Section*
38 *307. These experts shall not be active participants in the market*
39 *affected by the board action or decision.*

1 (B) If the board action or decision was not previously subject
2 to a public comment period, the director shall release the subject
3 matter of his or her investigation for a 30-day public comment
4 period and shall consider all comments received.

5 (C) If the director determines that the action or decision furthers
6 the public protection mission of the board and the impact on
7 competition is justified, the director may approve the action or
8 decision.

9 (D) If the director determines that the action furthers the public
10 protection mission of the board and the impact on competition is
11 justified, the director may approve the action or decision. If the
12 director finds the action or decision does not further the public
13 protection mission of the board or finds that the action or decision
14 is not justified, the director shall either refuse to approve it or
15 shall modify the action or decision to ensure that any restraints
16 of trade are related to, and advance, clearly articulated state law
17 or public policy.

18 (4) The director shall issue, and post on the department's
19 Internet Web site, his or her final written decision approving,
20 modifying, or disapproving the action or decision with an
21 explanation of the reasons and rationale behind the director's
22 decision within 90 days from receipt of the request from a
23 consumer or licensee. Notwithstanding any other law, the decision
24 of the director shall be final, except if the state or federal
25 constitution requires an appeal of the director's decision.

26 (d) The review set forth in paragraph (3) of subdivision (c) shall
27 not apply when an individual seeks review of disciplinary or other
28 action pertaining solely to that individual.

29 (e) The director shall report to the Chairs of the Senate Business,
30 Professions, and Economic Development Committee and the
31 Assembly Business and Professions Committee annually,
32 commencing March 1, 2017, regarding his or her disapprovals,
33 modifications, or findings from any audit, review, or monitoring
34 and evaluation conducted pursuant to this section. That report
35 shall be submitted in compliance with Section 9795 of the
36 Government Code.

37 (f) If the director has already reviewed a board action or
38 decision pursuant to this section or Section 313.1, the director
39 shall not review that action or decision again.

1 (g) *This section shall not be construed to affect, impede, or*
2 *delay any disciplinary actions of any board.*

3 *SEC. 2. Section 116 of the Business and Professions Code is*
4 *amended to read:*

5 116. (a) The director may audit and review, upon his or her
6 own initiative, or upon the request of a consumer or licensee,
7 inquiries and complaints regarding licensees, dismissals of
8 disciplinary cases, the opening, conduct, or closure of
9 investigations, informal conferences, and discipline short of formal
10 accusation by ~~the Medical Board of California, the allied health~~
11 ~~professional boards, and the California Board of Podiatric~~
12 ~~Medicine. The director may make recommendations for changes~~
13 ~~to the disciplinary system to the appropriate board, the Legislature,~~
14 ~~or both.~~ *any board or bureau within the department.*

15 (b) The director shall report to the ~~Chairpersons~~ *Chairs* of the
16 ~~Senate Business and Professions~~ *Business, Professions, and*
17 *Economic Development* Committee and the ~~Assembly Health~~
18 *Business and Professions* Committee annually, commencing March
19 1, ~~1995,~~ 2017, regarding his or her findings from any audit, review,
20 or monitoring and evaluation conducted pursuant to this section.
21 *This report shall be submitted in compliance with Section 9795 of*
22 *the Government Code.*

23 *SEC. 3. Section 153 of the Business and Professions Code is*
24 *amended to read:*

25 153. The director may investigate the work of the several
26 boards in his department and may obtain a copy of all records and
27 full and complete data in all official matters in possession of the
28 boards, their members, officers, or ~~employees, other than~~
29 ~~examination questions prior to submission to applicants at~~
30 ~~scheduled examinations.~~ *employees.*

31 *SEC. 4. Section 307 of the Business and Professions Code is*
32 *amended to read:*

33 307. The director may contract for the services of experts and
34 consultants where necessary to carry out ~~the provisions of this~~
35 chapter and may provide compensation and reimbursement of
36 expenses for ~~such~~ *those* experts and consultants in accordance with
37 state law.

38 *SEC. 5. Section 313.1 of the Business and Professions Code*
39 *is amended to read:*

1 313.1. (a) Notwithstanding any other ~~provision~~ of law to the
2 contrary, no rule or ~~regulation, except those relating to~~
3 ~~examinations and qualifications for licensure, regulation~~ and no
4 fee change proposed or promulgated by any of the boards,
5 commissions, or committees within the department, shall take
6 effect pending compliance with this section.

7 (b) The director shall be formally notified of and shall ~~be~~
8 ~~provided a full opportunity to review, in accordance with the~~
9 requirements of Article 5 (commencing with Section 11346) of
10 Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government
11 Code, *the requirements in subdivision (c) of Section 109*, and this
12 section, all of the following:

13 (1) All notices of proposed action, any modifications and
14 supplements thereto, and the text of proposed regulations.

15 (2) Any notices of sufficiently related changes to regulations
16 previously noticed to the public, and the text of proposed
17 regulations showing modifications to the text.

18 (3) Final rulemaking records.

19 (4) *All relevant facts, data, public comments, market conditions,*
20 *studies, or other documentary evidence pertaining to the market*
21 *impacted by the proposed regulation. This information shall be*
22 *included in the written decision of the director required under*
23 *paragraph (4) of subdivision (c) of Section 109.*

24 (c) The submission of all notices and final rulemaking records
25 to the director and the ~~completion of the director's review,~~
26 *approval*, as authorized by this section, shall be a precondition to
27 the filing of any rule or regulation with the Office of Administrative
28 Law. The Office of Administrative Law shall have no jurisdiction
29 to review a rule or regulation subject to this section until after the
30 ~~completion of the director's review and only then if the director~~
31 ~~has not disapproved it.~~ *approval*. The filing of any document with
32 the Office of Administrative Law shall be accompanied by a
33 certification that the board, commission, or committee has complied
34 with the requirements of this section.

35 (d) Following the receipt of any final rulemaking record subject
36 to subdivision (a), the director shall have the authority for a period
37 of 30 days to *approve a proposed rule or regulation or disapprove*
38 *a proposed rule or regulation on the ground that it is injurious to*
39 *the public health, safety, or ~~welfare.~~ welfare, or has an*
40 *impermissible anticompetitive effect. The director may modify a*

1 rule or regulation as a condition of approval. Any modifications
2 to regulations by the director shall be subject to a 30-day public
3 comment period before the director issues a final decision
4 regarding the modified regulation. If the director does not approve
5 the rule or regulation within the 30-day period, the rule or
6 regulation shall not be submitted to the Office of Administrative
7 Law and the rule or regulation shall have no effect.

8 (e) Final rulemaking records shall be filed with the director
9 within the one-year notice period specified in Section 11346.4 of
10 the Government Code. If necessary for compliance with this
11 section, the one-year notice period may be extended, as specified
12 by this subdivision.

13 (1) In the event that the one-year notice period lapses during
14 the director's 30-day review period, or within 60 days following
15 the notice of the director's disapproval, it may be extended for a
16 maximum of 90 days.

17 (2) If the director approves the final rulemaking record or
18 declines to take action on it within 30 days, record, the board,
19 commission, or committee shall have five days from the receipt
20 of the record from the director within which to file it with the
21 Office of Administrative Law.

22 (3) If the director disapproves a rule or regulation, it shall have
23 no force or effect unless, within 60 days of the notice of
24 disapproval, (A) the disapproval is overridden by a unanimous
25 vote of the members of the board, commission, or committee, and
26 (B) the board, commission, or committee files the final rulemaking
27 record with the Office of Administrative Law in compliance with
28 this section and the procedures required by Chapter 3.5
29 (commencing with Section 11340) of Part 1 of Division 3 of Title
30 2 of the Government Code. *This paragraph shall not apply to any*
31 *decision disapproved by the director under subdivision (c) of*
32 *Section 109.*

33 (f) ~~Nothing in this~~ This section shall *not* be construed to prohibit
34 the director from affirmatively approving a proposed rule,
35 regulation, or fee change at any time within the 30-day period after
36 it has been submitted to him or her, in which event it shall become
37 effective upon compliance with this section and the procedures
38 required by Chapter 3.5 (commencing with Section 11340) of Part
39 1 of Division 3 of Title 2 of the Government Code.

1 *SEC. 6. Section 2708 of the Business and Professions Code is*
2 *amended to read:*

3 2708. (a) The board shall appoint an executive officer who
4 shall perform the duties delegated by the board and who shall be
5 responsible to it for the accomplishment of those duties.

6 (b) The executive officer shall *not* be a ~~nurse currently licensed~~
7 *licensee* under this chapter and shall possess other qualifications
8 as determined by the board.

9 (c) The executive officer shall not be a member of the board.

10 (d) This section shall remain in effect only until January 1, 2018,
11 and as of that date is repealed, unless a later enacted statute, that
12 is enacted before January 1, 2018, deletes or extends that date.

13 ~~SECTION 1.~~

14 *SEC. 7. Section 4800 of the Business and Professions Code is*
15 *amended to read:*

16 4800. (a) There is in the Department of Consumer Affairs a
17 Veterinary Medical Board in which the administration of this
18 chapter is vested. The board consists of the following members:

19 (1) Four licensed veterinarians.

20 (2) One registered veterinary technician.

21 (3) Three public members.

22 (b) This section shall remain in effect only until January 1, 2021,
23 and as of that date is repealed.

24 (c) Notwithstanding any other law, the repeal of this section
25 renders the board subject to review by the appropriate policy
26 committees of the Legislature. However, the review of the board
27 shall be limited to those issues identified by the appropriate policy
28 committees of the Legislature and shall not involve the preparation
29 or submission of a sunset review document or evaluative
30 questionnaire.

31 ~~SEC. 2.~~

32 *SEC. 8. Section 4804.5 of the Business and Professions Code*
33 *is amended to read:*

34 4804.5. (a) The board may appoint a person exempt from civil
35 service who shall be designated as an executive officer and who
36 shall exercise the powers and perform the duties delegated by the
37 board and vested in him or her by this chapter.

38 (b) This section shall remain in effect only until January 1, 2021,
39 and as of that date is repealed.

1 *SEC. 9. Section 4825.1 of the Business and Professions Code*
2 *is amended to read:*

3 4825.1. These definitions shall govern the construction of this
4 chapter as it applies to veterinary medicine.

5 (a) “Diagnosis” means the act or process of identifying or
6 determining the health status of an animal through examination
7 and the opinion derived from that examination.

8 (b) “Animal” means any member of the animal kingdom other
9 than humans, and includes fowl, fish, and reptiles, wild or
10 domestic, whether living or dead.

11 (c) “Food animal” means any animal that is raised for the
12 production of an edible product intended for consumption by
13 humans. The edible product includes, but is not limited to, milk,
14 meat, and eggs. Food animal includes, but is not limited to, cattle
15 (beef or dairy), swine, sheep, poultry, fish, and amphibian species.

16 (d) “Livestock” includes all animals, poultry, aquatic and
17 amphibian species that are raised, kept, or used for profit. It does
18 not include those species that are usually kept as pets such as dogs,
19 cats, and pet birds, or companion animals, including equines.

20 (e) “*Compounding*,” for the purposes of veterinary medicine,
21 shall have the same meaning given in Section 1735 of Title 16 of
22 the California Code of Regulations, except that every reference
23 therein to “pharmacy” and “pharmacist” shall be replaced with
24 “veterinary premises” and “veterinarian,” and except that only
25 a licensed veterinarian or a licensed registered veterinarian
26 technician under direct supervision of a veterinarian may perform
27 compounding and shall not delegate to or supervise any part of
28 the performance of compounding by any other person.

29 *SEC. 10. Section 4826.3 is added to the Business and*
30 *Professions Code, to read:*

31 4826.3. (a) *Notwithstanding Section 4051, a veterinarian or*
32 *registered veterinarian technician under the direct supervision of*
33 *a veterinarian with a current and active license may compound a*
34 *drug for anesthesia, the prevention, cure, or relief of a wound,*
35 *fracture, bodily injury, or disease of an animal in a premises*
36 *currently and actively registered with the board and only under*
37 *the following conditions:*

38 (1) *Where there is no FDA-approved animal or human drug*
39 *that can be used as labeled or in an appropriate extralabel manner*

1 *to properly treat the disease, symptom, or condition for which the*
2 *drug is being prescribed.*

3 *(2) Where the compounded drug is not available from a*
4 *compounding pharmacy, outsourcing facility, or other*
5 *compounding supplier in a dosage form and concentration to*
6 *appropriately treat the disease, symptom, or condition for which*
7 *the drug is being prescribed.*

8 *(3) Where the need and prescription for the compounded*
9 *medication has arisen within an established*
10 *veterinarian-client-patient relationship as a means to treat a*
11 *specific occurrence of a disease, symptom, or condition observed*
12 *and diagnosed by the veterinarian in a specific animal that*
13 *threatens the health of the animal or will cause suffering or death*
14 *if left untreated.*

15 *(4) Where the quantity compounded does not exceed a quantity*
16 *demonstrably needed to treat a patient with which the veterinarian*
17 *has a current veterinarian-client-patient relationship.*

18 *(5) Except as specified in subdivision (c), where the compound*
19 *is prepared only with commercially available FDA-approved*
20 *animal or human drugs as active ingredients.*

21 *(b) A compounded veterinary drug may be prepared from an*
22 *FDA-approved animal or human drug for extralabel use only when*
23 *there is no approved animal or human drug that, when used as*
24 *labeled or in an appropriate extralabel manner will, in the*
25 *available dosage form and concentration, treat the disease,*
26 *symptom, or condition. Compounding from an approved human*
27 *drug for use in food-producing animals is not permitted if an*
28 *approved animal drug can be used for compounding.*

29 *(c) A compounded veterinary drug may be prepared from bulk*
30 *drug substances only when:*

31 *(1) The drug is compounded and dispensed by the veterinarian*
32 *to treat an individually identified animal patient under his or her*
33 *care.*

34 *(2) The drug is not intended for use in food-producing animals.*

35 *(3) If the drug contains a bulk drug substance that is a*
36 *component of any marketed FDA-approved animal or human drug,*
37 *there is a change between the compounded drug and the*
38 *comparable marketed drug made for an individually identified*
39 *animal patient that produces a clinical difference for that*
40 *individually identified animal patient, as determined by the*

1 veterinarian prescribing the compounded drug for his or her
2 patient.

3 (4) There are no FDA-approved animal or human drugs that
4 can be used as labeled or in an appropriate extralabel manner to
5 properly treat the disease, symptom, or condition for which the
6 drug is being prescribed.

7 (5) All bulk drug substances used in compounding are
8 manufactured by an establishment registered under Section 360
9 of Title 21 of the United States Code and are accompanied by a
10 valid certificate of analysis.

11 (6) The drug is not sold or transferred by the veterinarian
12 compounding the drug, except that the veterinarian shall be
13 permitted to administer the drug to a patient under his or her care
14 or dispense it to the owner or caretaker of an animal under his or
15 her care.

16 (7) Within 15 days of becoming aware of any product defect or
17 serious adverse event associated with any drug compounded by
18 the veterinarian from bulk drug substances, the veterinarian shall
19 report it to the federal Food and Drug Administration on Form
20 FDA 1932a.

21 (8) In addition to any other requirements, the label of any
22 veterinary drug compounded from bulk drug substances shall
23 indicate the species of the intended animal patient, the name of
24 the animal patient, and the name of the owner or caretaker of the
25 patient.

26 (d) Each compounded veterinary drug preparation shall meet
27 the labeling requirements of Section 4076 and Sections 1707.5
28 and 1735.4 of Title 16 of the California Code of Regulations, except
29 that every reference therein to “pharmacy” and “pharmacist”
30 shall be replaced by “veterinary premises” and “veterinarian,”
31 and any reference to “patient” shall be understood to refer to the
32 animal patient. In addition, each label on a compounded veterinary
33 drug preparation shall include withdrawal and holding times, if
34 needed, and the disease, symptom, or condition for which the drug
35 is being prescribed. Any compounded veterinary drug preparation
36 that is intended to be sterile, including for injection, administration
37 into the eye, or inhalation, shall in addition meet the labeling
38 requirements of Section 1751.2 of Title 16 of the California Code
39 of Regulations, except that every reference therein to “pharmacy”
40 and “pharmacist” shall be replaced by “veterinary premises” and

1 “veterinarian,” and any reference to “patient” shall be understood
2 to refer to the animal patient.

3 (e) Any veterinarian, registered veterinarian technician who is
4 under the direct supervision of a veterinarian, and veterinary
5 premises engaged in compounding shall meet the compounding
6 requirements for pharmacies and pharmacists stated by the
7 provisions of Article 4.5 (commencing with Section 1735) of Title
8 16 of the California Code of Regulations, except that every
9 reference therein to “pharmacy” and “pharmacist” shall be
10 replaced by “veterinary premises” and “veterinarian,” and any
11 reference to “patient” shall be understood to refer to the animal
12 patient:

13 (1) Section 1735.1 of Title 16 of the California Code of
14 Regulations.

15 (2) Subdivisions (d),(e), (f), (g), (h), (i), (j), (k), and (l) of Section
16 1735.2 of Title 16 of the California Code of Regulations.

17 (3) Section 1735.3 of Title 16 of the California Code of
18 Regulations, except that only a licensed veterinarian or registered
19 veterinarian technician may perform compounding and shall not
20 delegate to or supervise any part of the performance of
21 compounding by any other person.

22 (4) Section 1735.4 of Title 16 of the California Code of
23 Regulations.

24 (5) Section 1735.5 of Title 16 of the California Code of
25 Regulations.

26 (6) Section 1735.6 of Title 16 of the California Code of
27 Regulations.

28 (7) Section 1735.7 of Title 16 of the California Code of
29 Regulations.

30 (8) Section 1735.8 of Title 16 of the California Code of
31 Regulations.

32 (f) Any veterinarian, registered veterinarian technician under
33 the direct supervision of a veterinarian, and veterinary premises
34 engaged in sterile compounding shall meet the sterile compounding
35 requirements for pharmacies and pharmacists under Article 7
36 (commencing with Section 1751) of Title 16 of the California Code
37 of Regulations, except that every reference therein to “pharmacy”
38 and “pharmacist” shall be replaced by “veterinary premises” and
39 “veterinarian,” and any reference to “patient” shall be understood
40 to refer to the animal patient.

1 (g) *The California State Board of Pharmacy shall have authority*
2 *with the board to ensure compliance with this section and shall*
3 *have the right to inspect any veterinary premises engaged in*
4 *compounding, along with or separate from the board, to ensure*
5 *compliance with this section. The board is specifically charged*
6 *with enforcing this section with regard to its licensees.*

7 SEC. 11. *Section 4826.5 is added to the Business and*
8 *Professions Code, to read:*

9 4826.5. *Failure by a licensed veterinarian, registered*
10 *veterinarian technician, or veterinary premises to comply with the*
11 *provisions of this article shall be deemed unprofessional conduct*
12 *and constitute grounds for discipline.*

13 SEC. 12. *Section 4826.7 is added to the Business and*
14 *Professions Code, to read:*

15 4826.7. *The board may adopt regulations to implement the*
16 *provisions of this article.*

17 SEC. 13. *Section 4830 of the Business and Professions Code*
18 *is amended to read:*

19 4830. (a) This chapter does not apply to:

20 (1) Veterinarians while serving in any armed branch of the
21 military service of the United States or the United States
22 Department of Agriculture while actually engaged and employed
23 in their official capacity.

24 (2) Regularly licensed veterinarians in actual consultation from
25 other states.

26 (3) Regularly licensed veterinarians actually called from other
27 states to attend cases in this state, but who do not open an office
28 or appoint a place to do business within this state.

29 ~~(4) Veterinarians employed by the University of California~~
30 ~~while engaged in the performance of duties in connection with the~~
31 ~~College of Agriculture, the Agricultural Experiment Station, the~~
32 ~~School of Veterinary Medicine, or the agricultural extension work~~
33 ~~of the university or employed by the Western University of Health~~
34 ~~Sciences while engaged in the performance of duties in connection~~
35 ~~with the College of Veterinary Medicine or the agricultural~~
36 ~~extension work of the university.~~

37 ~~(5)~~

38 (4) Students in the School of Veterinary Medicine of the
39 University of California or the College of Veterinary Medicine of
40 the Western University of Health Sciences who participate in

1 diagnosis and treatment as part of their educational experience,
2 including those in off-campus educational programs under the
3 direct supervision of a licensed veterinarian in good standing, as
4 defined in paragraph (1) of subdivision (b) of Section 4848,
5 appointed by the University of California, Davis, or the Western
6 University of Health Sciences.

7 ~~(6)~~

8 (5) A veterinarian who is employed by the Meat and Poultry
9 Inspection Branch of the California Department of Food and
10 Agriculture while actually engaged and employed in his or her
11 official capacity. A person exempt under this paragraph shall not
12 otherwise engage in the practice of veterinary medicine unless he
13 or she is issued a license by the board.

14 ~~(7)~~

15 (6) Unlicensed personnel employed by the Department of Food
16 and Agriculture or the United States Department of Agriculture
17 when in the course of their duties they are directed by a veterinarian
18 supervisor to conduct an examination, obtain biological specimens,
19 apply biological tests, or administer medications or biological
20 products as part of government disease or condition monitoring,
21 investigation, control, or eradication activities.

22 (b) (1) For purposes of paragraph (3) of subdivision (a), a
23 regularly licensed veterinarian in good standing who is called from
24 another state by a law enforcement agency or animal control
25 agency, as defined in Section 31606 of the Food and Agricultural
26 Code, to attend to cases that are a part of an investigation of an
27 alleged violation of federal or state animal fighting or animal
28 cruelty laws within a single geographic location shall be exempt
29 from the licensing requirements of this chapter if the law
30 enforcement agency or animal control agency determines that it
31 is necessary to call the veterinarian in order for the agency or
32 officer to conduct the investigation in a timely, efficient, and
33 effective manner. In determining whether it is necessary to call a
34 veterinarian from another state, consideration shall be given to the
35 availability of veterinarians in this state to attend to these cases.
36 An agency, department, or officer that calls a veterinarian pursuant
37 to this subdivision shall notify the board of the investigation.

38 (2) Notwithstanding any other provision of this chapter, a
39 regularly licensed veterinarian in good standing who is called from
40 another state to attend to cases that are a part of an investigation

1 described in paragraph (1) may provide veterinary medical care
2 for animals that are affected by the investigation with a temporary
3 shelter facility, and the temporary shelter facility shall be exempt
4 from the registration requirement of Section 4853 if all of the
5 following conditions are met:

6 (A) The temporary shelter facility is established only for the
7 purpose of the investigation.

8 (B) The temporary shelter facility provides veterinary medical
9 care, shelter, food, and water only to animals that are affected by
10 the investigation.

11 (C) The temporary shelter facility complies with Section 4854.

12 (D) The temporary shelter facility exists for not more than 60
13 days, unless the law enforcement agency or animal control agency
14 determines that a longer period of time is necessary to complete
15 the investigation.

16 (E) Within 30 calendar days upon completion of the provision
17 of veterinary health care services at a temporary shelter facility
18 established pursuant to this section, the veterinarian called from
19 another state by a law enforcement agency or animal control agency
20 to attend to a case shall file a report with the board. The report
21 shall contain the date, place, type, and general description of the
22 care provided, along with a listing of the veterinary health care
23 practitioners who participated in providing that care.

24 (c) For purposes of paragraph (3) of subdivision (a), the board
25 may inspect temporary facilities established pursuant to this
26 section.

27 *SEC. 14. Section 4846.5 of the Business and Professions Code*
28 *is amended to read:*

29 4846.5. (a) Except as provided in this section, the board shall
30 issue renewal licenses only to those applicants that have completed
31 a minimum of 36 hours of continuing education in the preceding
32 two years.

33 (b) (1) Notwithstanding any other law, continuing education
34 hours shall be earned by attending courses relevant to veterinary
35 medicine and sponsored or cosponsored by any of the following:

36 (A) American Veterinary Medical Association (AVMA)
37 accredited veterinary medical colleges.

38 (B) Accredited colleges or universities offering programs
39 relevant to veterinary medicine.

40 (C) The American Veterinary Medical Association.

1 (D) American Veterinary Medical Association recognized
2 specialty or affiliated allied groups.

3 (E) American Veterinary Medical Association's affiliated state
4 veterinary medical associations.

5 (F) Nonprofit annual conferences established in conjunction
6 with state veterinary medical associations.

7 (G) Educational organizations affiliated with the American
8 Veterinary Medical Association or its state affiliated veterinary
9 medical associations.

10 (H) Local veterinary medical associations affiliated with the
11 California Veterinary Medical Association.

12 (I) Federal, state, or local government agencies.

13 (J) Providers accredited by the Accreditation Council for
14 Continuing Medical Education (ACCME) or approved by the
15 American Medical Association (AMA), providers recognized by
16 the American Dental Association Continuing Education
17 Recognition Program (ADA CERP), and AMA or ADA affiliated
18 state, local, and specialty organizations.

19 (2) Continuing education credits shall be granted to those
20 veterinarians taking self-study courses, which may include, but
21 are not limited to, reading journals, viewing video recordings, or
22 listening to audio recordings. The taking of these courses shall be
23 limited to no more than six hours biennially.

24 (3) The board may approve other continuing veterinary medical
25 education providers not specified in paragraph (1).

26 (A) The board has the authority to recognize national continuing
27 education approval bodies for the purpose of approving continuing
28 education providers not specified in paragraph (1).

29 (B) Applicants seeking continuing education provider approval
30 shall have the option of applying to the board or to a
31 board-recognized national approval body.

32 (4) For good cause, the board may adopt an order specifying,
33 on a prospective basis, that a provider of continuing veterinary
34 medical education authorized pursuant to paragraph (1) or (3) is
35 no longer an acceptable provider.

36 (5) Continuing education hours earned by attending courses
37 sponsored or cosponsored by those entities listed in paragraph (1)
38 between January 1, 2000, and January 1, 2001, shall be credited
39 toward a veterinarian's continuing education requirement under
40 this section.

1 (c) Every person renewing his or her license issued pursuant to
2 Section 4846.4, or any person applying for relicensure or for
3 reinstatement of his or her license to active status, shall submit
4 proof of compliance with this section to the board certifying that
5 he or she is in compliance with this section. Any false statement
6 submitted pursuant to this section shall be a violation subject to
7 Section 4831.

8 (d) This section shall not apply to a veterinarian's first license
9 renewal. This section shall apply only to second and subsequent
10 license renewals granted on or after January 1, 2002.

11 (e) The board shall have the right to audit the records of all
12 applicants to verify the completion of the continuing education
13 requirement. Applicants shall maintain records of completion of
14 required continuing education coursework for a period of four
15 years and shall make these records available to the board for
16 auditing purposes upon request. If the board, during this audit,
17 questions whether any course reported by the veterinarian satisfies
18 the continuing education requirement, the veterinarian shall provide
19 information to the board concerning the content of the course; the
20 name of its sponsor and cosponsor, if any; and specify the specific
21 curricula that was of benefit to the veterinarian.

22 (f) A veterinarian desiring an inactive license or to restore an
23 inactive license under Section 701 shall submit an application on
24 a form provided by the board. In order to restore an inactive license
25 to active status, the veterinarian shall have completed a minimum
26 of 36 hours of continuing education within the last two years
27 preceding application. The inactive license status of a veterinarian
28 shall not deprive the board of its authority to institute or continue
29 a disciplinary action against a licensee.

30 (g) Knowing misrepresentation of compliance with this article
31 by a veterinarian constitutes unprofessional conduct and grounds
32 for disciplinary action or for the issuance of a citation and the
33 imposition of a civil penalty pursuant to Section 4883.

34 (h) The board, in its discretion, may exempt from the continuing
35 education requirement any veterinarian who for reasons of health,
36 military service, or undue hardship cannot meet those requirements.
37 Applications for waivers shall be submitted on a form provided
38 by the board.

39 (i) The administration of this section may be funded through
40 professional license and continuing education provider fees. The

1 fees related to the administration of this section shall not exceed
2 the costs of administering the corresponding provisions of this
3 section.

4 (j) For those continuing education providers not listed in
5 paragraph (1) of subdivision (b), the board or its recognized
6 national approval agent shall establish criteria by which a provider
7 of continuing education shall be approved. The board shall initially
8 review and approve these criteria and may review the criteria as
9 needed. The board or its recognized agent shall monitor, maintain,
10 and manage related records and data. The board may impose an
11 application fee, not to exceed two hundred dollars (\$200)
12 biennially, for continuing education providers not listed in
13 paragraph (1) of subdivision (b).

14 (k) (1) ~~On or after~~ Beginning January 1, 2018, a licensed
15 veterinarian who renews his or her license shall complete a
16 minimum of one credit hour of continuing education on the
17 judicious use of medically important antimicrobial drugs every
18 four years as part of his or her continuing education requirements.

19 (2) For purposes of this subdivision, “medically important
20 antimicrobial drug” means an antimicrobial drug listed in Appendix
21 A of the federal Food and Drug Administration’s Guidance for
22 Industry #152, including critically important, highly important,
23 and important antimicrobial drugs, as that appendix may be
24 amended.

25 *SEC. 15. Section 4848.1 is added to the Business and*
26 *Professions Code, to read:*

27 *4848.1. (a) A veterinarian engaged in the practice of veterinary*
28 *medicine, as defined in Section 4826, employed by the University*
29 *of California while engaged in the performance of duties in*
30 *connection with the School of Veterinary Medicine or employed*
31 *by the Western University of Health Sciences while engaged in the*
32 *performance of duties in connection with the College of Veterinary*
33 *Medicine shall be licensed in California or shall hold a university*
34 *license issued by the board.*

35 *(b) An applicant is eligible to hold a university license if all of*
36 *the following are satisfied:*

37 *(1) The applicant is currently employed by the University of*
38 *California or Western University of Health Sciences as defined in*
39 *subdivision (a).*

1 (2) *Passes an examination concerning the statutes and*
2 *regulations of the Veterinary Medicine Practice Act, administered*
3 *by the board, pursuant to subparagraph (C) of paragraph (2) of*
4 *subdivision (a) of Section 4848.*

5 (3) *Successfully completes the approved educational curriculum*
6 *described in paragraph (5) of subdivision (b) of Section 4848 on*
7 *regionally specific and important diseases and conditions.*

8 (c) *A university license:*

9 (1) *Shall be numbered as described in Section 4847.*

10 (2) *Shall cease to be valid upon termination of employment by*
11 *the University of California or by the Western University of Health*
12 *Sciences.*

13 (3) *Shall be subject to the license renewal provisions in Section*
14 *4846.4.*

15 (4) *Shall be subject to denial, revocation, or suspension pursuant*
16 *to Sections 4875 and 4883.*

17 (d) *An individual who holds a University License is exempt from*
18 *satisfying the license renewal requirements of Section 4846.5.*

19 SEC. 16. *Section 4853.7 is added to the Business and*
20 *Professions Code, to read:*

21 4853.7. *A premise registration that is not renewed within five*
22 *years after its expiration may not be renewed and shall not be*
23 *restored, reissued, or reinstated thereafter. However, an*
24 *application for a new premise registration may be submitted and*
25 *obtained if both of the following conditions are met:*

26 (a) *No fact, circumstance, or condition exists that, if the premise*
27 *registration was issued, would justify its revocation or suspension.*

28 (b) *All of the fees that would be required for the initial premise*
29 *registration are paid at the time of application.*

30 SEC. 17. *Section 825 of the Government Code is amended to*
31 *read:*

32 825. (a) *Except as otherwise provided in this section, if an*
33 *employee or former employee of a public entity requests the public*
34 *entity to defend him or her against any claim or action against him*
35 *or her for an injury arising out of an act or omission occurring*
36 *within the scope of his or her employment as an employee of the*
37 *public entity and the request is made in writing not less than 10*
38 *days before the day of trial, and the employee or former employee*
39 *reasonably cooperates in good faith in the defense of the claim or*
40 *action, the public entity shall pay any judgment based thereon or*

1 any compromise or settlement of the claim or action to which the
2 public entity has agreed.

3 If the public entity conducts the defense of an employee or
4 former employee against any claim or action with his or her
5 reasonable good-faith cooperation, the public entity shall pay any
6 judgment based thereon or any compromise or settlement of the
7 claim or action to which the public entity has agreed. However,
8 where the public entity conducted the defense pursuant to an
9 agreement with the employee or former employee reserving the
10 rights of the public entity not to pay the judgment, compromise,
11 or settlement until it is established that the injury arose out of an
12 act or omission occurring within the scope of his or her
13 employment as an employee of the public entity, the public entity
14 is required to pay the judgment, compromise, or settlement only
15 if it is established that the injury arose out of an act or omission
16 occurring in the scope of his or her employment as an employee
17 of the public entity.

18 Nothing in this section authorizes a public entity to pay that part
19 of a claim or judgment that is for punitive or exemplary damages.

20 (b) Notwithstanding subdivision (a) or any other provision of
21 law, a public entity is authorized to pay that part of a judgment
22 that is for punitive or exemplary damages if the governing body
23 of that public entity, acting in its sole discretion except in cases
24 involving an entity of the state government, finds all of the
25 following:

26 (1) The judgment is based on an act or omission of an employee
27 or former employee acting within the course and scope of his or
28 her employment as an employee of the public entity.

29 (2) At the time of the act giving rise to the liability, the employee
30 or former employee acted, or failed to act, in good faith, without
31 actual malice and in the apparent best interests of the public entity.

32 (3) Payment of the claim or judgment would be in the best
33 interests of the public entity.

34 As used in this subdivision with respect to an entity of state
35 government, “a decision of the governing body” means the
36 approval of the Legislature for payment of that part of a judgment
37 that is for punitive damages or exemplary damages, upon
38 recommendation of the appointing power of the employee or
39 former employee, based upon the finding by the Legislature and
40 the appointing authority of the existence of the three conditions

1 for payment of a punitive or exemplary damages claim. The
2 provisions of subdivision (a) of Section 965.6 shall apply to the
3 payment of any claim pursuant to this subdivision.

4 The discovery of the assets of a public entity and the introduction
5 of evidence of the assets of a public entity shall not be permitted
6 in an action in which it is alleged that a public employee is liable
7 for punitive or exemplary damages.

8 The possibility that a public entity may pay that part of a
9 judgment that is for punitive damages shall not be disclosed in any
10 trial in which it is alleged that a public employee is liable for
11 punitive or exemplary damages, and that disclosure shall be
12 grounds for a mistrial.

13 (c) Except as provided in subdivision (d), if the provisions of
14 this section are in conflict with the provisions of a memorandum
15 of understanding reached pursuant to Chapter 10 (commencing
16 with Section 3500) of Division 4 of Title 1, the memorandum of
17 understanding shall be controlling without further legislative action,
18 except that if those provisions of a memorandum of understanding
19 require the expenditure of funds, the provisions shall not become
20 effective unless approved by the Legislature in the annual Budget
21 Act.

22 (d) The subject of payment of punitive damages pursuant to this
23 section or any other provision of law shall not be a subject of meet
24 and confer under the provisions of Chapter 10 (commencing with
25 Section 3500) of Division 4 of Title 1, or pursuant to any other
26 law or authority.

27 (e) Nothing in this section shall affect the provisions of Section
28 818 prohibiting the award of punitive damages against a public
29 entity. This section shall not be construed as a waiver of a public
30 entity's immunity from liability for punitive damages under Section
31 1981, 1983, or 1985 of Title 42 of the United States Code.

32 (f) (1) Except as provided in paragraph (2), a public entity shall
33 not pay a judgment, compromise, or settlement arising from a
34 claim or action against an elected official, if the claim or action is
35 based on conduct by the elected official by way of tortiously
36 intervening or attempting to intervene in, or by way of tortiously
37 influencing or attempting to influence the outcome of, any judicial
38 action or proceeding for the benefit of a particular party by
39 contacting the trial judge or any commissioner, court-appointed
40 arbitrator, court-appointed mediator, or court-appointed special

1 referee assigned to the matter, or the court clerk, bailiff, or marshal
2 after an action has been filed, unless he or she was counsel of
3 record acting lawfully within the scope of his or her employment
4 on behalf of that party. Notwithstanding Section 825.6, if a public
5 entity conducted the defense of an elected official against such a
6 claim or action and the elected official is found liable by the trier
7 of fact, the court shall order the elected official to pay to the public
8 entity the cost of that defense.

9 (2) If an elected official is held liable for monetary damages in
10 the action, the plaintiff shall first seek recovery of the judgment
11 against the assets of the elected official. If the elected official's
12 assets are insufficient to satisfy the total judgment, as determined
13 by the court, the public entity may pay the deficiency if the public
14 entity is authorized by law to pay that judgment.

15 (3) To the extent the public entity pays any portion of the
16 judgment or is entitled to reimbursement of defense costs pursuant
17 to paragraph (1), the public entity shall pursue all available
18 creditor's remedies against the elected official, including
19 garnishment, until that party has fully reimbursed the public entity.

20 (4) This subdivision shall not apply to any criminal or civil
21 enforcement action brought in the name of the people of the State
22 of California by an elected district attorney, city attorney, or
23 attorney general.

24 *(g) Notwithstanding subdivision (a), a public entity shall pay*
25 *for a judgment or settlement for treble damage antitrust awards*
26 *against a member of a regulatory board for an act or omission*
27 *occurring within the scope of his or her employment as a member*
28 *of a regulatory board.*

29 *SEC. 18. Section 11346.5 of the Government Code is amended*
30 *to read:*

31 11346.5. (a) The notice of proposed adoption, amendment, or
32 repeal of a regulation shall include the following:

33 (1) A statement of the time, place, and nature of proceedings
34 for adoption, amendment, or repeal of the regulation.

35 (2) Reference to the authority under which the regulation is
36 proposed and a reference to the particular code sections or other
37 provisions of law that are being implemented, interpreted, or made
38 specific.

1 (3) An informative digest drafted in plain English in a format
2 similar to the Legislative Counsel’s digest on legislative bills. The
3 informative digest shall include the following:

4 (A) A concise and clear summary of existing laws and
5 regulations, if any, related directly to the proposed action and of
6 the effect of the proposed action.

7 (B) If the proposed action differs substantially from an existing
8 comparable federal regulation or statute, a brief description of the
9 significant differences and the full citation of the federal regulations
10 or statutes.

11 (C) A policy statement overview explaining the broad objectives
12 of the regulation and the specific benefits anticipated by the
13 proposed adoption, amendment, or repeal of a regulation, including,
14 to the extent applicable, nonmonetary benefits such as the
15 protection of public health and safety, worker safety, or the
16 environment, the prevention of discrimination, the promotion of
17 fairness or social equity, and the increase in openness and
18 transparency in business and government, among other things.

19 (D) An evaluation of whether the proposed regulation is
20 inconsistent or incompatible with existing state regulations.

21 (4) Any other matters as are prescribed by statute applicable to
22 the specific state agency or to any specific regulation or class of
23 regulations.

24 (5) A determination as to whether the regulation imposes a
25 mandate on local agencies or school districts and, if so, whether
26 the mandate requires state reimbursement pursuant to Part 7
27 (commencing with Section 17500) of Division 4.

28 (6) An estimate, prepared in accordance with instructions
29 adopted by the Department of Finance, of the cost or savings to
30 any state agency, the cost to any local agency or school district
31 that is required to be reimbursed under Part 7 (commencing with
32 Section 17500) of Division 4, other nondiscretionary cost or
33 savings imposed on local agencies, and the cost or savings in
34 federal funding to the state.

35 For purposes of this paragraph, “cost or savings” means
36 additional costs or savings, both direct and indirect, that a public
37 agency necessarily incurs in reasonable compliance with
38 regulations.

39 (7) If a state agency, in proposing to adopt, amend, or repeal
40 any administrative regulation, makes an initial determination that

1 the action may have a significant, statewide adverse economic
2 impact directly affecting business, including the ability of
3 California businesses to compete with businesses in other states,
4 it shall include the following information in the notice of proposed
5 action:

6 (A) Identification of the types of businesses that would be
7 affected.

8 (B) A description of the projected reporting, recordkeeping, and
9 other compliance requirements that would result from the proposed
10 action.

11 (C) The following statement: “The (name of agency) has made
12 an initial determination that the (adoption/amendment/repeal) of
13 this regulation may have a significant, statewide adverse economic
14 impact directly affecting business, including the ability of
15 California businesses to compete with businesses in other states.
16 The (name of agency) (has/has not) considered proposed
17 alternatives that would lessen any adverse economic impact on
18 business and invites you to submit proposals. Submissions may
19 include the following considerations:

20 (i) The establishment of differing compliance or reporting
21 requirements or timetables that take into account the resources
22 available to businesses.

23 (ii) Consolidation or simplification of compliance and reporting
24 requirements for businesses.

25 (iii) The use of performance standards rather than prescriptive
26 standards.

27 (iv) Exemption or partial exemption from the regulatory
28 requirements for businesses.”

29 (8) If a state agency, in adopting, amending, or repealing any
30 administrative regulation, makes an initial determination that the
31 action will not have a significant, statewide adverse economic
32 impact directly affecting business, including the ability of
33 California businesses to compete with businesses in other states,
34 it shall make a declaration to that effect in the notice of proposed
35 action. In making this declaration, the agency shall provide in the
36 record facts, evidence, documents, testimony, or other evidence
37 upon which the agency relies to support its initial determination.

38 An agency’s initial determination and declaration that a proposed
39 adoption, amendment, or repeal of a regulation may have or will
40 not have a significant, adverse impact on businesses, including the

1 ability of California businesses to compete with businesses in other
2 states, shall not be grounds for the office to refuse to publish the
3 notice of proposed action.

4 (9) A description of all cost impacts, known to the agency at
5 the time the notice of proposed action is submitted to the office,
6 that a representative private person or business would necessarily
7 incur in reasonable compliance with the proposed action.

8 If no cost impacts are known to the agency, it shall state the
9 following:

10 “The agency is not aware of any cost impacts that a
11 representative private person or business would necessarily incur
12 in reasonable compliance with the proposed action.”

13 (10) A statement of the results of the economic impact
14 assessment required by subdivision (b) of Section 11346.3 or the
15 standardized regulatory impact analysis if required by subdivision
16 (c) of Section 11346.3, a summary of any comments submitted to
17 the agency pursuant to subdivision (f) of Section 11346.3 and the
18 agency’s response to those comments.

19 (11) The finding prescribed by subdivision (d) of Section
20 11346.3, if required.

21 (12) (A) A statement that the action would have a significant
22 effect on housing costs, if a state agency, in adopting, amending,
23 or repealing any administrative regulation, makes an initial
24 determination that the action would have that effect.

25 (B) The agency officer designated in paragraph ~~(14)~~ (15) shall
26 make available to the public, upon request, the agency’s evaluation,
27 if any, of the effect of the proposed regulatory action on housing
28 costs.

29 (C) The statement described in subparagraph (A) shall also
30 include the estimated costs of compliance and potential benefits
31 of a building standard, if any, that were included in the initial
32 statement of reasons.

33 (D) For purposes of model codes adopted pursuant to Section
34 18928 of the Health and Safety Code, the agency shall comply
35 with the requirements of this paragraph only if an interested party
36 has made a request to the agency to examine a specific section for
37 purposes of estimating the costs of compliance and potential
38 benefits for that section, as described in Section 11346.2.

39 (13) *If the regulatory action is submitted by a state board on*
40 *which a controlling number of decisionmakers are active market*

1 *participants in the market the board regulates, a statement that*
2 *the adopting agency has evaluated the impact of the proposed*
3 *regulation on competition, and that the proposed regulation*
4 *further a clearly articulated and affirmatively expressed state law*
5 *to restrain competition.*

6 ~~(13)~~

7 (14) A statement that the adopting agency must determine that
8 no reasonable alternative considered by the agency or that has
9 otherwise been identified and brought to the attention of the agency
10 would be more effective in carrying out the purpose for which the
11 action is proposed, would be as effective and less burdensome to
12 affected private persons than the proposed action, or would be
13 more cost effective to affected private persons and equally effective
14 in implementing the statutory policy or other provision of law. For
15 a major regulation, as defined by Section 11342.548, proposed on
16 or after November 1, 2013, the statement shall be based, in part,
17 upon the standardized regulatory impact analysis of the proposed
18 regulation, as required by Section 11346.3, as well as upon the
19 benefits of the proposed regulation identified pursuant to
20 subparagraph (C) of paragraph (3).

21 ~~(14)~~

22 (15) The name and telephone number of the agency
23 representative and designated backup contact person to whom
24 inquiries concerning the proposed administrative action may be
25 directed.

26 ~~(15)~~

27 (16) The date by which comments submitted in writing must
28 be received to present statements, arguments, or contentions in
29 writing relating to the proposed action in order for them to be
30 considered by the state agency before it adopts, amends, or repeals
31 a regulation.

32 ~~(16)~~

33 (17) Reference to the fact that the agency proposing the action
34 has prepared a statement of the reasons for the proposed action,
35 has available all the information upon which its proposal is based,
36 and has available the express terms of the proposed action, pursuant
37 to subdivision (b).

38 ~~(17)~~

39 (18) A statement that if a public hearing is not scheduled, any
40 interested person or his or her duly authorized representative may

1 request, no later than 15 days prior to the close of the written
2 comment period, a public hearing pursuant to Section 11346.8.

3 ~~(18)~~

4 (19) A statement indicating that the full text of a regulation
5 changed pursuant to Section 11346.8 will be available for at least
6 15 days prior to the date on which the agency adopts, amends, or
7 repeals the resulting regulation.

8 ~~(19)~~

9 (20) A statement explaining how to obtain a copy of the final
10 statement of reasons once it has been prepared pursuant to
11 subdivision (a) of Section 11346.9.

12 ~~(20)~~

13 (21) If the agency maintains an Internet Web site or other similar
14 forum for the electronic publication or distribution of written
15 material, a statement explaining how materials published or
16 distributed through that forum can be accessed.

17 ~~(21)~~

18 (22) If the proposed regulation is subject to Section 11346.6, a
19 statement that the agency shall provide, upon request, a description
20 of the proposed changes included in the proposed action, in the
21 manner provided by Section 11346.6, to accommodate a person
22 with a visual or other disability for which effective communication
23 is required under state or federal law and that providing the
24 description of proposed changes may require extending the period
25 of public comment for the proposed action.

26 (b) The agency representative designated in paragraph~~(14)~~ (15)
27 of subdivision (a) shall make available to the public upon request
28 the express terms of the proposed action. The representative shall
29 also make available to the public upon request the location of
30 public records, including reports, documentation, and other
31 materials, related to the proposed action. If the representative
32 receives an inquiry regarding the proposed action that the
33 representative cannot answer, the representative shall refer the
34 inquiry to another person in the agency for a prompt response.

35 (c) This section shall not be construed in any manner that results
36 in the invalidation of a regulation because of the alleged inadequacy
37 of the notice content or the summary or cost estimates, or the
38 alleged inadequacy or inaccuracy of the housing cost estimates, if
39 there has been substantial compliance with those requirements.

1 *SEC. 19. Section 11349 of the Government Code is amended*
2 *to read:*

3 11349. The following definitions govern the interpretation of
4 this chapter:

5 (a) “Necessity” means the record of the rulemaking proceeding
6 demonstrates by substantial evidence the need for a regulation to
7 effectuate the purpose of the statute, court decision, or other
8 provision of law that the regulation implements, interprets, or
9 makes specific, taking into account the totality of the record. For
10 purposes of this standard, evidence includes, but is not limited to,
11 facts, studies, and expert opinion.

12 (b) “Authority” means the provision of law which permits or
13 obligates the agency to adopt, amend, or repeal a regulation.

14 (c) “Clarity” means written or displayed so that the meaning of
15 regulations will be easily understood by those persons directly
16 affected by them.

17 (d) “Consistency” means being in harmony with, and not in
18 conflict with or contradictory to, existing statutes, court decisions,
19 or other provisions of law.

20 (e) “Reference” means the statute, court decision, or other
21 provision of law which the agency implements, interprets, or makes
22 specific by adopting, amending, or repealing a regulation.

23 (f) “Nonduplication” means that a regulation does not serve the
24 same purpose as a state or federal statute or another regulation.
25 This standard requires that an agency proposing to amend or adopt
26 a regulation must identify any state or federal statute or regulation
27 which is overlapped or duplicated by the proposed regulation and
28 justify any overlap or duplication. This standard is not intended
29 to prohibit state agencies from printing relevant portions of
30 enabling legislation in regulations when the duplication is necessary
31 to satisfy the clarity standard in paragraph (3) of subdivision (a)
32 of Section 11349.1. This standard is intended to prevent the
33 indiscriminate incorporation of statutory language in a regulation.

34 (g) “Competitive impact” means that the record of the
35 rulemaking proceeding or other documentation demonstrates that
36 the regulation is authorized by a clearly articulated and
37 affirmatively expressed state law, that the regulation furthers the
38 public protection mission of the state agency, and that the impact
39 on competition is justified in light of the applicable regulatory
40 rationale for the regulation.

1 *SEC. 20. Section 11349.1 of the Government Code is amended*
2 *to read:*

3 11349.1. (a) The office shall review all regulations adopted,
4 amended, or repealed pursuant to the procedure specified in Article
5 5 (commencing with Section 11346) and submitted to it for
6 publication in the California Code of Regulations Supplement and
7 for transmittal to the Secretary of State and make determinations
8 using all of the following standards:

9 (1) Necessity.

10 (2) Authority.

11 (3) Clarity.

12 (4) Consistency.

13 (5) Reference.

14 (6) Nonduplication.

15 (7) *For those regulations submitted by a state board on which*
16 *a controlling number of decisionmakers are active market*
17 *participants in the market the board regulates, the office shall*
18 *review for competitive impact.*

19 In reviewing regulations pursuant to this section, the office shall
20 restrict its review to the regulation and the record of the rulemaking
21 ~~proceeding~~ *except as directed in subdivision (h)*. The office shall
22 approve the regulation or order of repeal if it complies with the
23 standards set forth in this section and with this chapter.

24 (b) In reviewing proposed regulations for the criteria in
25 subdivision (a), the office may consider the clarity of the proposed
26 regulation in the context of related regulations already in existence.

27 (c) The office shall adopt regulations governing the procedures
28 it uses in reviewing regulations submitted to it. The regulations
29 shall provide for an orderly review and shall specify the methods,
30 standards, presumptions, and principles the office uses, and the
31 limitations it observes, in reviewing regulations to establish
32 compliance with the standards specified in subdivision (a). The
33 regulations adopted by the office shall ensure that it does not
34 substitute its judgment for that of the rulemaking agency as
35 expressed in the substantive content of adopted regulations.

36 (d) The office shall return any regulation subject to this chapter
37 to the adopting agency if any of the following occur:

38 (1) The adopting agency has not prepared the estimate required
39 by paragraph (6) of subdivision (a) of Section 11346.5 and has not

1 included the data used and calculations made and the summary
2 report of the estimate in the file of the rulemaking.

3 (2) The agency has not complied with Section 11346.3.
4 “Noncompliance” means that the agency failed to complete the
5 economic impact assessment or standardized regulatory impact
6 analysis required by Section 11346.3 or failed to include the
7 assessment or analysis in the file of the rulemaking proceeding as
8 required by Section 11347.3.

9 (3) The adopting agency has prepared the estimate required by
10 paragraph (6) of subdivision (a) of Section 11346.5, the estimate
11 indicates that the regulation will result in a cost to local agencies
12 or school districts that is required to be reimbursed under Part 7
13 (commencing with Section 17500) of Division 4, and the adopting
14 agency fails to do any of the following:

15 (A) Cite an item in the Budget Act for the fiscal year in which
16 the regulation will go into effect as the source from which the
17 Controller may pay the claims of local agencies or school districts.

18 (B) Cite an accompanying bill appropriating funds as the source
19 from which the Controller may pay the claims of local agencies
20 or school districts.

21 (C) Attach a letter or other documentation from the Department
22 of Finance which states that the Department of Finance has
23 approved a request by the agency that funds be included in the
24 Budget Bill for the next following fiscal year to reimburse local
25 agencies or school districts for the costs mandated by the
26 regulation.

27 (D) Attach a letter or other documentation from the Department
28 of Finance which states that the Department of Finance has
29 authorized the augmentation of the amount available for
30 expenditure under the agency’s appropriation in the Budget Act
31 which is for reimbursement pursuant to Part 7 (commencing with
32 Section 17500) of Division 4 to local agencies or school districts
33 from the unencumbered balances of other appropriations in the
34 Budget Act and that this augmentation is sufficient to reimburse
35 local agencies or school districts for their costs mandated by the
36 regulation.

37 (4) The proposed regulation conflicts with an existing state
38 regulation and the agency has not identified the manner in which
39 the conflict may be resolved.

1 (5) The agency did not make the alternatives determination as
2 required by paragraph (4) of subdivision (a) of Section 11346.9.

3 (6) *The office decides that the record of the rulemaking*
4 *proceeding or other documentation for the proposed regulation*
5 *does not demonstrate that the regulation is authorized by a clearly*
6 *articulated and affirmatively expressed state law, that the*
7 *regulation does not further the public protection mission of the*
8 *state agency, or that the impact on competition is not justified in*
9 *light of the applicable regulatory rationale for the regulation.*

10 (e) The office shall notify the Department of Finance of all
11 regulations returned pursuant to subdivision (d).

12 (f) The office shall return a rulemaking file to the submitting
13 agency if the file does not comply with subdivisions (a) and (b)
14 of Section 11347.3. Within three state working days of the receipt
15 of a rulemaking file, the office shall notify the submitting agency
16 of any deficiency identified. If no notice of deficiency is mailed
17 to the adopting agency within that time, a rulemaking file shall be
18 deemed submitted as of the date of its original receipt by the office.
19 A rulemaking file shall not be deemed submitted until each
20 deficiency identified under this subdivision has been corrected.

21 (g) Notwithstanding any other law, return of the regulation to
22 the adopting agency by the office pursuant to this section is the
23 exclusive remedy for a failure to comply with subdivision (c) of
24 Section 11346.3 or paragraph (10) of subdivision (a) of Section
25 11346.5.

26 (h) *The office may designate, employ, or contract for the services*
27 *of independent antitrust or applicable economic experts when*
28 *reviewing proposed regulations for competitive impact. When*
29 *reviewing a regulation for competitive impact, the office shall do*
30 *all of the following:*

31 (1) *If the Director of Consumer Affairs issued a written decision*
32 *pursuant to subdivision (c) of Section 109 of the Business and*
33 *Professions Code, the office shall review and consider the decision*
34 *and all supporting documentation in the rulemaking file.*

35 (2) *Consider whether the anticompetitive effects of the proposed*
36 *regulation are clearly outweighed by the public policy merits.*

37 (3) *Provide a written opinion setting forth the office's findings*
38 *and substantive conclusions under paragraph (2), including, but*
39 *not limited to, whether rejection or modification of the proposed*
40 *regulation is necessary to ensure that restraints of trade are related*

1 *to and advance the public policy underlying the applicable*
2 *regulatory rationale.*

3 *SEC. 21. No reimbursement is required by this act pursuant*
4 *to Section 6 of Article XIII B of the California Constitution because*
5 *the only costs that may be incurred by a local agency or school*
6 *district will be incurred because this act creates a new crime or*
7 *infraction, eliminates a crime or infraction, or changes the penalty*
8 *for a crime or infraction, within the meaning of Section 17556 of*
9 *the Government Code, or changes the definition of a crime within*
10 *the meaning of Section 6 of Article XIII B of the California*
11 *Constitution.*

O