2010 LEGISLATION OF INTEREST

SB 294	Author:	Negrete McLeod
	Title:	Regulatory Boards Sunset Review Dates
	Introduced:	February 25, 2009 Amended June 16, 2010 to include sunset review dates
	Status:	Assembly Committee on Appropriations
	Summary:	Changes the sunset review dates on various boards, bureaus, and programs within the Department of Consumer Affairs. This bill would extend our sunset date to January 1, 2013.
	Position:	

SB 1172	Author:	Negrete McLeod
	Title:	Regulatory Board Probation and Diversion Programs
	Introduced:	February 18, 2010
	Status:	Assembly Committee on Business Professions and Consumer Protection
	Summary:	Limits the retention requirements on records for treatment and rehab of substance-abusing licentiates, authorizes specified healing art boards to roder a licensee to cease practice due to amajor vioaltion or if the licensee has been ordered to undergo a clinical diagnostic evaluation, and orders specified healing arts boards to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.
	Position:	

S. 3002	Author:	McCain
	Title:	Dietary Supplement Safety Act of 2010
	Introduced:	February 4, 2010
	Status:	Committee of Health, Education, Labor and Pensions
	Summary:	To amend the Federal Food, Drug, and Cosmetic Act to more effectively regulate dietary supplements that may pose safety risks unknown to consumers.
	Position:	

AMENDED IN ASSEMBLY JUNE 16, 2010

AMENDED IN ASSEMBLY SEPTEMBER 4, 2009

AMENDED IN ASSEMBLY JULY 1, 2009

AMENDED IN ASSEMBLY JUNE 8, 2009

AMENDED IN SENATE MARCH 31, 2009

SENATE BILL No. 294

Introduced by Senator Negrete McLeod

February 25, 2009

~~An act to amend Sections 27, 116, 160, 726, 802.1 803, 803.5, 803.6, 1695.5, 2365, 2663, 2666, 2715, 2770.7, 3534.1, 3534.5, 4365, 4369, and 4870 of, to add Sections 1695.7, 1699.2, 2365.5, 2372, 2669.2, 2770.16, 2770.18, 2835.7, 3534.12, 4375, 4870.5, and 4873.2 to, to add Article 10.1 (commencing with Section 720) to Chapter 1 of Division 2 of, to add and repeal Section 2719 of, and to repeal Article 4.7 (commencing with Section 1695) of Chapter 4 of, Article 15 (commencing with Section 2360) of Chapter 5 of, Article 5.5 (commencing with Section 2662) of Chapter 5.7 of, Article 3.1 (commencing with Section 2770) of Chapter 6 of, Article 6.5 (commencing with Section 3534) of Chapter 7.7 of, Article 21 (commencing with Section 4360) of Chapter 9 of, and Article 3.5 (commencing with Section 4860) of Chapter 11 of, Division 2 of, the Business and Professions Code, relating to healing arts.~~ *An act to amend Sections 2001, 2020, 2531, 2569, 2570.19, 2701, 2708, 2920, 2933, 3010.5, 3014.6, 3504, 3512, 3685, 3686, 4800, 4804.5, 4928, 4934, 4990, 4990.04, 5000, 5015.6, 5510, 5517, 5552.5, 5620, 5621, 5622, 5810, 6510, 6710, 6714, 7000.5, 7011, 7200, 7303, 8000, 8005, 8520, 8528, 8710, 11506, 18602, 18613, 22259 of, and to amend and repeal Section 2531.75 of, the Business and Professions Code, and to amend*

Existing law provides for the regulation of registered dispensing opticians by the Medical Board of California and provides that the powers and duties of the board in that regard shall be subject to review by the Joint Committee on Boards, Commissions, and Consumer Protection as if those provisions were scheduled to become inoperative on July 1, 2003, and repealed on January 1, 2004.

This bill would make the powers and duties of the board subject to that review as if those provisions were scheduled to be repealed on January 1, 2014.

Existing law provides for the licensure and regulation of specified healing arts licensees by the Acupuncture Board and the Board of Behavioral Sciences (BBS). Existing law authorizes the Acupuncture Board to appoint an executive officer and requires BBS to appoint an executive officer. Under existing law, these provisions are repealed on January 1, 2011.

Under this bill, these provisions would be repealed on January 1, 2013.

Existing law provides for the licensure and regulation of registered nurses by the Board of Registered Nursing and requires the board to appoint an executive officer. Under existing law, these provisions are repealed on January 1, 2013.

This bill would instead repeal these provisions on January 1, 2012.

Existing law provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law provides that these regulatory provisions are repealed on January 1, 2013.

This bill would provide that those regulatory provisions are repealed on January 1, 2014.

(2) Existing law also provides for the licensure and regulation of various profession and vocations by boards within the department, including, the California Board of Accountancy, the California Architects Board, the Landscape Architects Technical Committee, Professional Fiduciaries Bureau, the Board for Professional Engineers and Land Surveyors, and the State Board of Guide Dogs for the Blind. Existing law requires or authorizes, with certain exceptions, these boards to appoint an executive officer or a registrar. With respect to the Professional Fiduciaries Bureau, existing law authorizes the Governor to appoint the chief of the bureau. Under existing law, these provisions will become inoperative on July 1, 2011, and will be repealed on January 1, 2012.

shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

~~This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.~~

This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 20. Section 4928 of the Business and Professions Code is amended to read:

4928. The Acupuncture Board, which consists of seven members, shall enforce and administer this chapter. ~~The appointing powers, as described in Section 4929, may appoint to the board a person who was a member of the prior board prior to the repeal of that board on January 1, 2006.~~

This section shall remain in effect only until January 1, ~~2011~~ *2013*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ *2013*, deletes or extends that date.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 21. Section 4934 of the Business and Professions Code is amended to read:

4934. (a) The board, by and with the approval of the director, may employ personnel necessary for the administration of this chapter, and the board, by and with the approval of the director, may appoint an executive officer who is exempt from the provisions of the Civil Service Act.

(b) This section shall remain in effect only until January 1, ~~2011~~ *2013*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ *2013*, deletes or extends that date.

SEC. 22. Section 4990 of the Business and Professions Code is amended to read:

4990. (a) There is in the Department of Consumer Affairs, a Board of Behavioral Sciences that consists of the following members:

(1) Two state licensed clinical social workers.

(2) One state licensed educational psychologist.

AMENDED IN ASSEMBLY JUNE 22, 2010

AMENDED IN SENATE MAY 11, 2010

AMENDED IN SENATE APRIL 27, 2010

AMENDED IN SENATE APRIL 12, 2010

SENATE BILL No. 1172

Introduced by Senator Negrete McLeod

February 18, 2010

An act to amend Section 156.1 of, and to add Sections ~~315.2, 315.4, and 315.6~~ *315.2 and 315.4* to, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

SB 1172, as amended, Negrete McLeod. Regulatory boards: diversion programs.

(1) Existing law provides for the regulation of specified professions and vocations by various boards, as defined, within the Department of Consumer Affairs. Under existing law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs are required to retain all records and documents pertaining to those services for 3 years or until they are audited, whichever occurs first. Under existing law, those records and documents are required to be kept confidential and are not subject to discovery or subpoena.

This bill would specify that those records and documents shall be kept for 3 years and kept confidential and are not subject to discovery or subpoena unless otherwise expressly provided by law.

(2) Existing law provides for the licensure and regulation of various healing arts by boards within the Department of Consumer Affairs. Under existing law, these boards are authorized to issue, deny, suspend, and revoke licenses based on various grounds and to take disciplinary action against their licensees.

Existing law establishes diversion and recovery programs to identify and rehabilitate dentists, osteopathic physicians and surgeons, physical therapists, physical therapy assistants, registered nurses, physician assistants, pharmacists and intern pharmacists, veterinarians, and registered veterinary technicians whose competency may be impaired due to, among other things, alcohol and drug abuse.

The bill would require a healing arts board to order a licensee to cease practice if the licensee tests positive for any prohibited substance under the terms of the licensee's probation or diversion program. The bill would also authorize a board to adopt regulations authorizing it to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation, as specified. ~~Except as provided, the bill would prohibit a healing arts board from disclosing to the public that a licensee is participating in a board diversion program.~~ *The bill would provide that these provisions do not affect the Board of Registered Nursing.*

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

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

SECTION 1. Section 156.1 of the Business and Professions Code is amended to read:

156.1. (a) Notwithstanding any other provision of law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs shall retain all records and documents pertaining to those services until such time as these records and documents have been reviewed for audit by the department. These records and documents shall be retained for three years from the date of the last treatment or service rendered to that licentiate, after which time the records and documents may be purged and destroyed by the contract vendor. This provision shall supersede any other

provision of law relating to the purging or destruction of records pertaining to those treatment and rehabilitation programs.

(b) Unless otherwise expressly provided by statute or regulation, all records and documents pertaining to services for the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs provided by any contract vendor to the department or to any board within the department shall be kept confidential and are not subject to discovery or subpoena.

(c) With respect to all other contracts for services with the department or any board within the department other than those set forth in subdivision (a), the director or chief deputy director may request an examination and audit by the department's internal auditor of all performance under the contract. For this purpose, all documents and records of the contract vendor in connection with such performance shall be retained by such vendor for a period of three years after final payment under the contract. Nothing in this section shall affect the authority of the State Auditor to conduct any examination or audit under the terms of Section 8546.7 of the Government Code.

SEC. 2. Section 315.2 is added to the Business and Professions Code, to read:

315.2. (a) A board, as described in Section 315, shall order a licensee of the board to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

SEC. 3. Section 315.4 is added to the Business and Professions Code, to read:

315.4. (a) A board, as described in Section 315, may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical

diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

~~SEC. 4. Section 315.6 is added to the Business and Professions Code, to read:~~

~~315.6. Unless otherwise authorized by statute or regulation, a board, as described in Section 315, shall not disclose to the public that a licensee is participating in a board diversion program unless participation was ordered as a term of probation. However, a board shall disclose to the public any restrictions that are placed on a licensee's practice as a result of the licensee's participation in a board diversion program provided that the disclosure does not contain information linking the restriction to the licensee's participation in the board's diversion program.~~

(d) This section shall have no effect on the Board of Registered Nursing pursuant to Article 3.1 (commencing with Section 2770) of Chapter 6 of Division 2.

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S 3002 IS

111th CONGRESS

2d Session

S. 3002

To amend the Federal Food, Drug, and Cosmetic Act to more effectively regulate dietary supplements that may pose safety risks unknown to consumers.

IN THE SENATE OF THE UNITED STATES

February 4, 2010

Mr. MCCAIN (for himself and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to more effectively regulate dietary supplements that may pose safety risks unknown to consumers.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Dietary Supplement Safety Act of 2010'.

SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) Definitions- Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

`(ss) Dietary Supplement Facility- The term `dietary supplement facility' means any business or operation engaged in manufacturing, packaging, holding, distributing, labeling, or licensing a dietary supplement for consumption in the United States.'.

(b) Registration of Dietary Supplement Facilities-

(1) ADULTERATED FOOD- Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by inserting at the end the following:

`(j) If it is a dietary supplement that is manufactured, packaged, held, distributed, labeled, or licensed by a dietary supplement facility that is not registered with the Secretary.'.

(2) REGISTRATION OF FOOD FACILITIES- Section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) is amended--

(A) in the section heading, by striking `facilities' and inserting `and dietary supplement facilities'; and

(B) in subsection (a)--

(i) in paragraph (2)--

(I) by striking `An entity' and inserting the following:

`(A) FOOD FACILITIES- An entity'; and

(II) by adding at the end the following:

`(B) DIETARY SUPPLEMENT FACILITIES-

`(i) IN GENERAL- A dietary supplement facility (referred to in the section as a `dietary supplement registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the dietary supplement registrant conducts business. At the time of registration,

the dietary supplement registrant shall also file with the Secretary a list of all dietary supplements manufactured, packaged, held, distributed, labeled, or licensed by the facility. Such list shall be prepared in such form and manner as the Secretary may prescribe, and shall be accompanied by a full list of the ingredients contained in each dietary supplement, and a copy of the labeling used by the facility for each dietary supplement.

`(ii) UPDATES- Each dietary supplement registrant shall update the registrant's registration annually on or before the anniversary date of the registrant's initial registration. Each dietary supplement registrant shall also update the registrant's registration to include information regarding any new dietary supplement, or reformulation of an existing dietary supplement, on or before the date such dietary supplement is marketed for consumption in the United States.'; and

(ii) in paragraph (3), by inserting `or dietary supplement registrant' after `notify the registrant'.

(c) New Dietary Ingredients- Section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b) is amended--

(1) by striking subsection (a) and inserting the following:

`(a) In General- A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless there is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. The Secretary shall keep confidential any information provided under this subsection for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.';

(2) in subsection (c), by striking `was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994' and inserting `is not included on the list of `Accepted Dietary Ingredients', to be prepared, published, and maintained by the Secretary'; and

(3) by adding at the end the following:

`(d) Maintaining Substantiation File- Any person submitting information to the Secretary under subsection (a) shall create and maintain a scientifically reasonable substantiation file relating to the claim that the dietary ingredient or dietary supplement will reasonably be expected to be safe. The substantiation file shall be prepared and maintained in such form and manner as the Secretary may prescribe and shall be available for review and inspection by the Secretary upon request.

`(e) Evidence of Compliance- A dietary supplement facility or retailer shall, prior to manufacturing, packaging, holding, distributing, labeling, or licensing the dietary supplement, obtain adequate written evidence from the preceding responsible entity in the chain of commerce that the product is registered as required by section 415 and that the requirements of subsection (a) have been met. Such facility or retailer shall maintain such evidence of compliance for review and inspection by the Secretary upon request.'.

(d) Civil Monetary Penalty for Non-Compliance- Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

`(h) Civil Monetary Penalty for Non-Compliance- Notwithstanding the provisions of subsection (a), any person who manufacturers, packages, holds, distributes, labels, or licenses a dietary supplement in violation of section 301, 402, 413, 415, 501, 502, 505, or 761, may, in addition to other penalties imposed in this section, be fined not more than twice the gross profits or other proceeds derived from the manufacture, packaging, holding, distribution, labeling, or license of such dietary supplement.'.

(e) Adverse Event Reporting for Dietary Supplements- Section 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa-1) is amended--

(1) in the section heading, by striking `serious adverse' and inserting `adverse';

(2) in subsection (a), by adding at the end the following:

`(4) ADVERSE EVENT REPORT- The term `adverse event report' means a report of non-serious adverse events that is required to be submitted to the Secretary under subsection (b).';

(3) in subsection (b)(1)--

(A) by striking `The manufacturer' and inserting the following:

`(A) SERIOUS ADVERSE EVENTS- The manufacturer'; and

(B) by adding at the end the following:

`(B) NON-SERIOUS ADVERSE EVENTS- The manufacturer, packer, holder, distributor, labeler, or licensee of a dietary supplement, whose name appears on the label of a dietary supplement marketed in the United States, shall submit to the Secretary, in such form and manner as the Secretary shall determine, a compilation report of all non-serious adverse events associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.';

(4) in subsection (c)(1), by adding at the end: `The responsible person shall annually submit to the Secretary a compilation report of all non-serious adverse events received during the preceding year.';

(5) in subsection (e)(1), by adding at the end: `The responsible person shall maintain records related to each annually submitted adverse event report for a period of 3 years.'; and

(6) in subsection (f), by striking `or an adverse event report voluntarily submitted' and inserting `or a non-serious adverse report submitted annually'.

(f) Recall Authority for Dietary Supplements-

(1) IN GENERAL- Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

`SEC. 418. RECALL AUTHORITY FOR DIETARY SUPPLEMENTS.

`(a) Recall Authority-

`(1) CEASE DISTRIBUTION AND NOTIFICATION ORDER-

`(A) IN GENERAL- If the Secretary finds there is a reasonable probability that a dietary supplement or a product marketed or sold as a dietary supplement would cause serious, adverse health consequences or death, or is adulterated or misbranded, the Secretary shall issue a cease distribution and notification order requiring the person named in the order to immediately--

`(i) cease distribution of such dietary supplement or a product marketed or sold as a dietary supplement;

`(ii) notify distributors, importers, retailers, and consumers of the order; and

`(iii) instruct those distributors, importers, retailers, and consumers to cease distributing, importing, selling, and using the dietary supplement.

`(B) INFORMAL HEARING- An order described in subparagraph (A) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the dietary supplement or the product marketed or sold as a dietary supplement. The person subject to the order shall have 5 days to notify the Secretary of the person's intent to challenge the order. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

`(2) RECALL-

`(A) IN GENERAL- If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the dietary supplement or the product marketed or sold as a dietary supplement with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the dietary supplement recall will occur and shall require periodic reports to the Secretary describing the progress of the recall. The Secretary shall have the authority to initiate the action prescribed in this subparagraph regardless of whether or not the person subject to the order elects to exercise the right to challenge the initial order as permitted under paragraph (1).

`(B) CONTENT OF AMENDED ORDER- An amended order under subparagraph (A)--

`(i) shall not include recall of the dietary supplement or the product marketed or sold as a dietary

supplement from individuals; and

`(ii) shall provide for notice to individuals, at the expense of retailers and to the satisfaction of the Secretary, subject to the risks associated with the use of such dietary supplement.

`(C) NOTIFICATION- In providing the notice required by subparagraph (B)(ii), if a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705 (b).'.

END