



California Regulatory Notice Register

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PROPOSED ACTION ON REGULATIONS

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The *California Regulatory Notice Register* is an official state publication of the Office of Administrative Law containing notices of proposed regulatory actions by state regulatory agencies to adopt, amend or repeal regulations contained in the California Code of Regulations. The effective period of a notice of proposed regulatory action by a state agency in the *California Regulatory Notice Register* shall not exceed one year [Government Code § 11346.4(b)]. It is suggested, therefore, that issues of the *California Regulatory Notice Register* be retained for a minimum of 18 months.

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**PROPOSED ACTION ON
REGULATIONS**

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**TITLE 4. CALIFORNIA HORSE
RACING BOARD**

**NOTICE OF PROPOSAL TO AMEND
RULE 1588, HORSE INELIGIBLE TO START IN
A RACE**

The California Horse Racing Board (Board or CHRB) proposes to amend the regulation described below after considering all comments, objections or recommendations regarding the proposed action.

PROPOSED REGULATORY ACTION

The California Horse Racing Board (Board or CHRB) proposes to amend Board Rule 1588, Horse Ineligible to Start in a Race, to provide that a horse is ineligible to start in any race in California if it is on the Veterinarian's List in another racing jurisdiction, unless with prior approval of the stewards.

PUBLIC HEARING

The Board will hold a public hearing starting at **9:30 a.m., Thursday, October 23, 2014**, or as soon after that as business before the Board will permit, at the **Santa Anita Park Race Track, Baldwin Terrace Room, 285 West Huntington Drive, Arcadia, California**. At the hearing, any person may present statements or arguments orally or in writing about the proposed action described in the informative digest. It is requested, but not required, that persons making oral comments at the hearing submit a written copy of their testimony.

WRITTEN COMMENT PERIOD

Any interested persons, or their authorized representative, may submit written comments about the proposed regulatory action to the Board. The written comment period closes at **5:00 p.m. on October 20, 2014**. The Board must receive all comments at that time; how-

ever, written comments may still be submitted at the public hearing. Submit comments to:

Leeland Turner, Regulation Analyst
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
Telephone: (916) 263-6026
Fax: (916) 263-6042
E-mail: ltturner@chrb.ca.gov

AUTHORITY AND REFERENCE

Authority cited: Sections 19440 and 19562, Business and Professions Code. Reference Sections: 19440, and 19562, Business and Professions Code.

Business and Professions Code section 19440 and 19562 give the Board jurisdiction and supervision over meetings in California where horse races with wagering on their results are held, authorizes the Board to adopt, amend or repeal regulations, and allows for the Board to delegate any of its powers to the stewards.

**INFORMATIVE DIGEST/POLICY STATEMENT
OVERVIEW**

Business and Professions Code section 19440 states that the Board shall have all powers necessary and proper to enable it to adopt rules and regulations for the protection of the public and the control of horse racing. Business and Professions Code section 19562 states that the Board may prescribe rules, regulations, and conditions on all California horse races with wagering on their results. Rule 1866, Veterinarian's List, defines the California Veterinarian's List and states the general rules and uses of the list. It states a horse may be placed on the list due to veterinary treatment, physical distress, injury, lameness, unsoundness, or infirmity. Rule 1588, Horse Ineligible to Start in a Race, identifies the circumstances that make a horse ineligible to start in a race, including being on the California Veterinarian's List. The Board proposes amending Rule 1588, Horse Ineligible to Start a Race. The proposed amendment adds a new subsection 1588(j), which provides that a horse on the Veterinarian's List in another racing jurisdiction is ineligible to start in a race in California unless it has prior approval of the stewards. A horse is placed on a Veterinarian's list for many reasons, including an injury or illness causing the horse to be unsound to race, or issues related to medication. Allowing a horse on a Veterinarian's List entry into a California horserace poses a safety hazard to the horse, its jockey, and other entrants of a race. It is common practice in California for the Official Veterinarian to consult the Veterinarian's Lists of other racing jurisdictions when determin-

ing a horse's eligibility to race. This is done using InCompass Solutions, a software system developed by the Jockey Club, a national organization, formed in New York in 1894, dedicated to the improvement of thoroughbred breeding and racing. InCompass Solutions stores and maintains Veterinarian's List information of participating racing jurisdictions. Because there is currently no rule prohibiting horses on another racing jurisdiction's Veterinarian's List from racing in California, the practice of checking for such horses competing in California races is inconsistent. Some Official Veterinarians are diligent in determining whether an unfamiliar horse is on a Veterinarian's List of another jurisdiction, and other Official Veterinarians are less diligent. The addition of subsection 1588(j), which prohibits entry of horses on a Veterinarian's List in another jurisdiction is necessary to ensure all horses deemed unfit to race by another racing jurisdiction face a higher and consistent level of scrutiny before being allowed to race in California.

Recognizing that unforeseen problems with administrative procedures, as well as the time of relocation of the horse to California, may delay the removal of the horse from another jurisdiction's Veterinarian's List, the proposed addition of subsection 1588(j) provides California stewards the flexibility to approve the race eligibility of a horse found on another jurisdiction's Veterinarian's list. Although the stewards may consult with the Official Veterinarian when approving the race eligibility of a horse, they are the body with the authority to make such decisions. CHRB Rule 1580, Control over Entries and Declarations, provides that all entries and declarations are under the supervision of the stewards.

All other proposed changes to Rule 1588 are for the purpose of clarification, consistency, renumbering and grammar.

ANTICIPATED BENEFITS OF PROPOSAL

The proposed amendment to Rule 1588 promotes the protection of horse racing participants and improves equine safety. Veterinarians are not able to catch every possible issue with a horse that would place it on the Veterinarian's List. Some issues are hidden, presenting signs intermittently, or not at all. Utilizing Veterinarian's Lists from other racing jurisdictions is a helpful tool, putting more scrutiny on horses that have previously been determined to be unfit to race. Utilizing the Veterinarian's Lists from other racing jurisdictions also prevents a trainer or owner with a horse determined to be unfit in another jurisdiction from moving the horse to California to avoid any required rehabilitation, in the hope of hiding its issue from California veterinarians.

The proposed amendment to Rule 1588 will help to prevent jockey injuries, saving the racing industry money by reducing the cost of workers' compensation claims, and will also prevent horse injury or loss. Therefore the proposed rulemaking will benefit the health and safety of the jockey and the horse which are essential elements in the horseracing industry.

CONSISTENCY EVALUATION

During the process of developing this amendment, the CHRB has conducted a search of any similar regulations on this topic and has concluded that this amendment is neither inconsistent nor incompatible with existing state regulations.

DISCLOSURE REGARDING THE PROPOSED ACTION/RESULTS OF THE ECONOMIC IMPACT ANALYSIS

Mandate on local agencies and school districts: none.
Cost or savings to any state agency: none.

Cost to any local agency or school district that must be reimbursed in accordance with Government Code Section 17500 through 17630: none.

Other non-discretionary cost or savings imposed upon local agencies: none.

Cost or savings in federal funding to the state: none.

The Board has made an initial determination that the proposed amendment to Rule 1588 will not have a significant statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination: none.

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

Significant effect on housing costs: none.

The adoption of the proposed amendment to Rule 1588 will not (1) create or eliminate jobs within California; (2) create new businesses or eliminate existing businesses within California; or (3) affect the expansion of businesses currently doing business within California. The proposed amendment to Rule 1588 promotes the protection of worker and equine safety as well as the public's interest in a fair and honest race product.

Effect on small businesses: none. The proposal to amend Rule 1588 does not affect small businesses because horse racing associations in California are not classified as small businesses under Government Code Section 11342.610.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subdivision (a)(13), the Board must determine that no reasonable alternative considered by the Board, or that has otherwise been identified and brought to the attention of the Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome on affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the substance of the proposed action and requests for copies of the proposed text of the regulation, the initial statement of reasons, the modified text of the regulation, if any, and other information upon which the rulemaking is based should be directed to:

Leeland Turner, Regulation Analyst
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
Telephone: (916) 263-6026
Fax: (916) 263-6042
E-mail: ltturner@chr.ca.gov

If the person named above is not available, interested parties may contact:

Andrea Ogden, Manager
Policy and Regulations
Telephone: (916) 263-6033

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its offices at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulation, and the initial statement of reasons. Copies of these documents, or any of the information upon which the proposed rulemaking is based, may be obtained by contacting Leeland Turner, or the alter-

native contact person at the address, phone number or e-mail address listed above.

AVAILABILITY OF MODIFIED TEXT

After holding a hearing and considering all timely and relevant comments received, the Board may adopt the proposed regulation substantially as described in this notice. If modifications are made which are sufficiently related to the originally proposed text, the modified text, with changes clearly marked, shall be made available to the public for at least 15 days prior to the date on which the Board adopts the regulation. Requests for copies of any modified regulation should be sent to the attention of Leeland Turner at the address stated above. The Board will accept written comments on the modified regulation for 15 days after the date on which it is made available.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Requests for copies of the final statement of reasons, which will be available after the Board has adopted the proposed regulation in its current or modified form, should be sent to the attention of Leeland Turner at the address stated above.

BOARD WEB ACCESS

The Board will have the entire rulemaking file available for inspection throughout the rulemaking process at its website. The rulemaking file consists of the notice, the proposed text of the regulations and the initial statement of reasons. The Board's website address is: www.chrb.ca.gov.

TITLE 4. CALIFORNIA HORSE RACING BOARD

NOTICE OF PROPOSAL TO AMEND RULE 1858, TEST SAMPLE REQUIRED

The California Horse Racing Board (Board or CHRHB) proposes to amend the regulation described below after considering all comments, objections or recommendations regarding the proposed action.

PROPOSED REGULATORY ACTION

The CHRHB proposes to amend Board Rule 1858, Test Sample Required, to remove the upper limit of nine horses designated each day for testing by the Equine

Medical Director, the stewards, or the official veterinarian. The proposed amendment adds language to include every horse registered to race at an inclosure, nominated, or pre-entered as subject to testing. For the purposes of the regulation the proposed amendment defines "registered to race at an inclosure," as a horse that has papers on file with a racing association or racing fair under the jurisdiction of the Board.

PUBLIC HEARING

The Board will hold a public hearing starting at **9:30 a.m., Thursday, October 23, 2014**, or as soon after that as business before the Board will permit, at the **Santa Anita Park Race Track, Baldwin Terrace Room, 285 West Huntington Drive, Arcadia, California**. At the hearing, any person may present statements or arguments orally or in writing about the proposed action described in the informative digest. It is requested, but not required, that persons making oral comments at the hearing submit a written copy of their testimony.

WRITTEN COMMENT PERIOD

Any interested persons, or their authorized representative, may submit written comments about the proposed regulatory action to the Board. The written comment period closes at **5:00 p.m. on October 20, 2014**. The Board must receive all comments at that time; however, written comments may still be submitted at the public hearing. Submit comments to:

Leeland Turner, Regulation Analyst
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
Telephone: (916) 263-6026
Fax: (916) 263-6042
E-mail: ltturner@chr.ca.gov

AUTHORITY AND REFERENCE

Authority cited: Sections 19440, 19562, and 19580, Business and Professions Code. Reference Sections: 19440, 19562, and 19580, Business and Professions Code.

Business and Professions Code sections 19440 and 19562 give the Board jurisdiction and supervision over meetings in California where horse races with wagering on their results are held, authorizes the Board to adopt, amend or repeal regulations, and allows for the Board to delegate any of its powers to the stewards. Business and Professions Code section 19580 provides that the Board shall adopt regulations to establish policies, guidelines,

and penalties relating to equine medication in order to preserve and enhance the integrity of horseracing in California.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 19440 states that the Board shall have all powers necessary and proper to enable it to adopt rules and regulations for the protection of the public and the control of horse racing. Business and Professions Code section 19562 states that the Board may prescribe rules, regulations, and conditions on all California horse races with wagering on their results. Business and Professions Code section 19580 provides that the Board shall adopt regulations to establish policies, guidelines, and penalties relating to equine medication in order to preserve and enhance the integrity of horseracing in California. Board Rule 1858, Test Sample Required, currently requires blood and urine samples to be collected from the winner of every race, horses placing second or third in a stakes race with a gross purse of \$75,000 or more, and not less than six or more than nine other horses selected by the Equine Medical Director, the stewards or the official veterinarian. Additionally, Rule 1858 provides that every horse within the inclosure or entered to race is subject to testing, and no person having care of a horse shall refuse to submit it for testing when directed by the stewards or official veterinarian.

The Board proposes amending Rule 1858 by reorganizing it into three subsections: 1858(a), which will define which and how many horses are tested daily; 1858(b), which will define what horses are subject to testing; and 1858(b)(1) which defines, for the purposes of the regulation, the phrase "registered to race at an inclosure."

In subsection 1858(a), the proposed amendment removes the upper limit of nine horses designated for testing by the Equine Medical Director, the stewards, or the official veterinarian. Removing the upper limit is necessary to make Rule 1858 more effective and bring it in line with current testing practices. Rule 1858 currently provides that blood and urine samples shall be taken daily from specified horses; however, the Board also tests all claimed horses, and horses at unique events, such as the Breeders' Cup and the Champion of Champions. The additional tests can put the number of horses tested beyond the current nine horse upper limit. Removing the upper limit will increase the effectiveness of Rule 1858 as a deterrent by giving more flexibility to the veterinarians and stewards in choosing which horses to test.

In subsection 1858(b), the proposed amendment provides that every horse registered to race at an inclosure,

nominated, or pre-entered, in any race is subject to testing. This allows for testing horses located outside of the inclosure. This is necessary because a drug can be administered well before a race, be undetectable in post-race testing, and still have a potentially profound performance enhancing effect at race time. Erythropoietin is an example of such a drug. Adding that nominated and pre-entered horses are subject to testing would provide the regulatory authority for the Board's out-of-competition (OOC) testing program for the Breeders' Cup and other stakes. Currently, the Board relies on the Breeders' Cup entry provisions for its OOC testing. The proposed amendment would provide authority to have test samples taken in other states for horses nominated to California stakes, and to sample horses for other states as the CHRB currently does for the Kentucky Horse Racing Commission for the Kentucky Derby.

The proposed amendment adds 1858(b)(1) which defines, for the purposes of the regulation, "registered to race at an inclosure" as when the horse's registration papers are on file with a racing association under the jurisdiction of the Board. Currently, horsemen must apply for stalls if they plan to run at a meeting — thus "registering" their horses that will occupy the stalls as potential entrants. However, under the proposed amendment to Rule 1858, "registering" a horse with a racing association regardless of the horse's location (off-site) is a new concept. Any horse that potentially may run at a race meeting could be required to register in advance with the association; thus, horses not located at the inclosure would be available for testing.

ANTICIPATED BENEFITS OF PROPOSAL

The proposed amendment to Rule 1858 promotes the protection of worker and equine safety, as well as the public's interest in a fair and honest race product, by increasing the efficiency and flexibility of the equine sample testing program. The proposed amendment would increase the effectiveness of Rule 1858 as a deterrent by removing the upper limit on the number of horses tested, and by allowing for horses outside the inclosure to be tested.

CONSISTENCY EVALUATION

During the process of developing this amendment, the CHRB conducted a search of any similar regulations on this topic and concluded that this amendment is neither inconsistent nor incompatible with existing state regulations.

DISCLOSURE REGARDING THE PROPOSED ACTION/RESULTS OF THE ECONOMIC IMPACT ANALYSIS

Mandate on local agencies and school districts: none.
 Cost or savings to any state agency: none.

Cost to any local agency or school district that must be reimbursed in accordance with Government Code Section 17500 through 17630: none.

Other non-discretionary cost or savings imposed upon local agencies: none.

Cost or savings in federal funding to the state: none.

The Board has made an initial determination that the proposed amendment to Rule 1858 will not have a significant statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination: none.

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

Significant effect on housing costs: none.

The adoption of the proposed amendment to Rule 1858 will not (1) create or eliminate jobs within California; (2) create new businesses or eliminate existing businesses within California; or (3) affect the expansion of businesses currently doing business within California. (4) The adoption of the proposed amendment will increase horseracing employee and equine safety.

Effect on small businesses: none. The proposal to amend Rule 1858 does not affect small businesses because horse racing associations in California are not classified as small businesses under Government Code Section 11342.610.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subdivision (a)(13), the Board must determine that no reasonable alternative considered by the Board, or that has otherwise been identified and brought to the attention of the Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome on affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the substance of the proposed action and requests for copies of the proposed text of the regulation, the initial statement of reasons, the modified text of the regulation, if any, and other information upon which the rulemaking is based should be directed to:

Leeland Turner, Regulation Analyst
California Horse Racing Board
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Sacramento, CA 95825
Telephone: (916) 263-6026
Fax: (916) 263-6042
E-mail: ltturner@chrh.ca.gov

If the person named above is not available, interested parties may contact:

Andrea Ogden, Manager
Policy and Regulations
Telephone: (916) 263-6033

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

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AVAILABILITY OF MODIFIED TEXT

After holding a hearing and considering all timely and relevant comments received, the Board may adopt the proposed regulation substantially as described in this notice. If modifications are made which are sufficiently related to the originally proposed text, the modified text, with changes clearly marked, shall be made available to the public for at least 15 days prior to the date on which the Board adopts the regulations. Requests for copies of any modified regulations should be sent to the attention of Leeland Turner at the address stated above. The Board will accept written comments on the modified regulation for 15 days after the date on which it is made available.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Requests for copies of the final statement of reasons, which will be available after the Board has adopted the proposed regulation in its current or modified form, should be sent to the attention of Leeland Turner at the address stated above.

BOARD WEB ACCESS

The Board will have the entire rulemaking file available for inspection throughout the rulemaking process at its website. The rulemaking file consists of the notice, the proposed text of the regulations and the initial statement of reasons. The Board's website address is: www.chrb.ca.gov.

TITLE 13. AIR RESOURCES BOARD

NOTICE OF PUBLIC HEARING TO CONSIDER PROPOSED AMENDMENTS TO THE LEV III CRITERIA POLLUTANT REQUIREMENTS FOR LIGHT- AND MEDIUM-DUTY VEHICLES, THE HYBRID ELECTRIC VEHICLE TEST PROCEDURES, AND THE HEAVY-DUTY OTTO-CYCLE AND HEAVY-DUTY DIESEL TEST PROCEDURES

The Air Resources Board (ARB or Board) will conduct a public hearing at the time and place noted below to consider proposed amendments to the Low-Emission Vehicle (LEV III) criteria pollutant emissions requirements for light- and medium-duty vehicles and to the hybrid electric vehicle test procedures. In addition, a number of conforming and editorial modifications to the non-methane organic gas test procedures, heavy-duty Otto-cycle test procedures, heavy-duty diesel test procedures, and Environmental Performance Label specifications are being considered.

DATE: October 23, 2014

TIME: 9:00 a.m.

PLACE: South Coast Air Quality Management
District
21865 Copley Drive
Diamond Bar, California 91765

This item will be considered at a two-day meeting of the Board, which will commence at 9:00 a.m., October 23, 2014, and may continue at 8:30 a.m., on October 24, 2014. This item may not be considered until October 24, 2014. Please consult the agenda for the hearing, which will be available at least 10 days before October 23, 2014, to determine the day on which this item will be considered.

INFORMATIVE DIGEST OF PROPOSED ACTION
AND POLICY STATEMENT OVERVIEW
PURSUANT TO GOVERNMENT
CODE 11346.5(a)(3)

Sections Affected: Proposed amendments to California Code of Regulations, title 13, sections 1900, 1956.8, 1961.2, 1962.2, 1965, 1976, and 1978; and to the following documents incorporated by reference therein: “California 2015 and Subsequent Model Criteria Pollutant Exhaust Emission Standards and Test Procedures and 2017 and Subsequent Model Greenhouse Gas Exhaust Emission Standards and Test Procedures for Passenger Cars, Light–Duty Trucks, and Medium–Duty Vehicles,” as last amended December 6, 2012; “California Non–Methane Organic Gas Test Procedures,” as last amended December 6, 2012; “California Evaporative Emission Standards and Test Procedures for 2001 and Subsequent Model Motor Vehicles,” as last amended December 6, 2012; “California Refueling Emission Standards and Test Procedures for 2001 and Subsequent Model Motor Vehicles,” as last amended March 22, 2012; “California Exhaust Emission Standards and Test Procedures for 2004 and Subsequent Model Heavy–Duty Otto–Cycle Engines,” as last amended April 18, 2013; “California Exhaust Emission Standards and Test Procedures for 2004 and Subsequent Model Heavy–Duty Diesel Engines and Vehicles,” as last amended April 18, 2013; “California Exhaust Emission Standards and Test Procedures for 2018 and Subsequent Model Zero–Emission Vehicles and Hybrid Electric Vehicles, in the Passenger Car, Light–Duty Truck and Medium–Duty Vehicle Classes,” as last amended May 30, 2014; and “California Environmental Performance Label Specifications for 2009 and Subsequent Model Year Passenger Cars, Light–Duty Trucks, and Medium–Duty Passenger Vehicles,” as last amended March 22, 2012. Note: There is a pending ARB rulemaking that also amends the “California Exhaust Emission Standards and Test Procedures for 2004 and Subsequent Model Heavy–Duty Otto–Cycle Engines” and the “California Exhaust Emission Standards and Test Procedures for 2004 and Subsequent Model Heavy–Duty Diesel Engines and Vehicles”; the text proposed with this notice identifies these other pending amendments.

Proposed adoption of new “California Non–Methane Organic Gas Test Procedures for 2017 and Subsequent Model Year Vehicles,” incorporated by reference in title 13, CCR, section 1961.2.

Documents Incorporated by Reference:

Although there are a number of documents that are incorporated by reference in the above–mentioned test

procedures, only those documents that are newly incorporated by this rulemaking are noted below.

The following documents are incorporated by reference in the “California Exhaust Emission Standards and Test Procedures for 2018 and Subsequent Model Zero–Emission Vehicles and Hybrid Electric Vehicles, in the Passenger Car, Light–Duty Truck and Medium–Duty Vehicle Classes”:

- SAE International, 2012. J1634: “Battery Electric Vehicle Energy Consumption and Range Test Procedure,” as revised by SAE International in October, 2012. Copyrighted.
- SAE International, 2010. J1711: “Recommended Practice for Measuring the Exhaust Emissions and Fuel Economy of Hybrid–Electric Vehicles, Including Plug–in Hybrid Vehicles,” as revised by SAE International in June, 2010. Copyrighted.

Background and Effect of the Proposed Rulemaking:

Overview

In order to address the need to further reduce vehicle emissions and achieve California’s goals of meeting ambient air quality standards and reducing climate changing greenhouse gas emissions (GHG), in January 2012, California developed the Advanced Clean Cars (ACC) program. The ACC program incorporates three elements that combine the control of smog–causing (criteria pollutant) emissions and GHG into a single coordinated package of requirements for model years 2015 through 2025. These three elements include: the Low–Emission Vehicle III (LEV III) regulations, the Zero–Emission Vehicle (ZEV) regulations, and the Clean Fuels Outlet regulations. (Ultimately, the Clean Fuels Outlet regulation update was not finalized by the Board because of the passage of legislation, Assembly Bill 8 (Chap. 401, Stats 2013), which included dedicated funding for hydrogen fueling infrastructure to support the market launch of hydrogen fuel cell vehicles.)

Subsequent to the adoption of the ACC program, the U.S. Environmental Protection Agency (U.S. EPA) finalized the federal Tier 3¹ program designed to reduce criteria pollutants from light–duty vehicles from model year 2017 through 2025. The Tier 3 program essentially mirrors California’s LEV III program in both structure and requirements and was developed in a cooperative effort with ARB. Consistent with ARB’s comments on

¹ Federal Register, Volume 76, No. 129 / Wednesday, July 6, 2011 / Final Rule, Environmental Protection Agency and National Highway Traffic Safety Administration, “Revisions and Additions to Motor Vehicle Fuel Economy Label.” <http://www.gpo.gov/fdsys/pkg/FR-2011-07-06/pdf/2011-14291.pdf>

the Tier 3 program as originally proposed by U.S. EPA, staff is proposing to align with a number of features of the Tier 3 program.

Tier 3 also restructures and updates the exhaust and evaporative emission test procedures in the Code of Federal Regulations (CFR). California's test procedures extensively reference the CFR to assure that manufacturers can use the same test procedures to certify both their federal and California vehicles. Accordingly, staff is proposing to update the references to the CFR in California's test procedures.

Staff is also proposing to update the Hybrid Electric Vehicle Test Procedures to accommodate new configurations of plug-in hybrid electric vehicles, modify manufacturer reporting requirements to include additional information on advanced vehicles, revise the California Environmental Performance Label Specifications to accommodate LEV III vehicles, and update the Heavy-Duty Otto-Cycle and Heavy-Duty Diesel Test Procedures to incorporate the currently applicable versions of the CFR.

Current Proposal

The proposed major modifications to the LEV III program and the Hybrid Electric Vehicle Test Procedures are identified below. In addition, a limited number of modifications are being proposed to the Heavy-Duty Engine and Vehicle test procedures to parallel the changes being proposed to the LEV III regulations. Minor modifications to the regulations are not listed here but are identified in the Staff Report.

LEV III Criteria Pollutant Exhaust Emission Regulations

- Incorporate 40 CFR Part 1066 into the California test procedures;
- Establish an oxides of nitrogen (NOx) cap for the medium-duty vehicle LEV395, ULEV340, LEV630, and ULEV570 emission categories and sunset these categories after the 2021 model year;
- Establish LEV III non-methane organic gas (NMOG) plus NOx 150,000-mile mass emission exhaust standards that apply at high-altitude conditions for the LEV160, ULEV125, ULEV70, ULEV50, SULEV30, and SULEV20 emission categories;
- Establish a NMOG+NOx fleet average phase-in for medium-duty LEV III vehicles as an alternative to the current phase-in requirement that relies on percentages of LEV III vehicles being sold each year;
- Establish more stringent NMOG+NOx fleet average requirements for small volume manufacturers;

- Eliminate less stringent in-use supplemental federal test procedure (SFTP) NMOG+NOx standards for light-duty vehicles;
- Require LEV II vehicles included in the LEV III SFTP NMOG+NOx fleet average to certify to bins and be subject to their bin value at full-useful life;
- For fuel-flexible vehicles, require SFTP testing on all the fuels that they are designed to use;
- Require medium-duty vehicle test groups that certify to a LEV III NMOG+NOx emission category for federal test procedure (FTP) compliance to also certify to the equivalent LEV III emission category for SFTP compliance;
- Align with federal SFTP fuel enrichment limitations;
- Establish more stringent SFTP particulate matter standards for light-duty vehicles to reflect current test data;
- Clarify that exhaust emission standards that apply at 50 degrees Fahrenheit only apply at 4,000 miles;
- Clarify that Direct Ozone Reduction technology credits can only be used to demonstrate compliance with FTP exhaust emission standards;
- Clarify how the NMOG+NOx Contribution Factor for off-vehicle charge capable hybrid electric vehicles (also known as plug-in hybrid electric vehicles or PHEVs) should be calculated for LEV II vehicles and for 2018 and subsequent model year vehicles;
- Incorporate a methodology for calculating fleet average credits and debits for medium-duty vehicles including conversion of credits and debits from the current Vehicle Equivalent Credits to fleet average credits;
- Clarify that, for in-use verification testing, any vehicle tested to demonstrate compliance with FTP particulate matter standards must also be tested to demonstrate compliance with SFTP particulate matter standards;
- Clarify how to use FTP test values in place of SC03 test values in SFTP particulate matter composite value calculations for medium-duty vehicles;
- Clarify that the non-methane hydrocarbon to NMOG conversion factor for SFTP applies only to gasoline-fueled vehicles;
- Clarify that the LEV III SFTP carbon monoxide standard does not apply to LEV II vehicles or cleaner federal vehicles included in the LEV III SFTP NMOG+NOx fleet average;
- Allow ARB to participate in the selection process of the emission data vehicles chosen for LEV III PM testing by a manufacturer; and

- Exempt a federal Bin 8, Bin 85, or Bin 110 vehicle that is sold in California as an alternative to a LEV II vehicle under the Cleaner Federal Vehicle provisions from 50 degrees Fahrenheit testing requirements.

Evaporative Emission Regulations

- Incorporate 40 CFR Part 1066 into the California test procedures;
- Adopt an effective diameter leak standard and test procedure;
- Adopt evaporative canister bleed test in-use requirements;
- Extend the carry-over period for LEV II zero-evaporative emission certified vehicles;
- Adopt evaporative emission testing provisions for vehicles equipped with an auxiliary (non-road) engine;
- Amend the alternate phase-in compliance basis; and
- Clarify fuel requirements for evaporative emission durability mileage accumulation.

Refueling Emission Regulations

- Expand On-board Refueling Vapor Recovery applicability to include complete vehicles over 14,000 lbs. GVWR;
- Allow federal test fuel for fuel-flexible vehicles; and
- Modify the exemption criteria for diesel refueling emission testing.

Reporting Requirements

- Require manufacturers to provide additional vehicle-specific information when reporting projected future sales of hydrogen vehicles in California that is used for infrastructure planning purposes.
- Require manufacturers to provide information on projected future sales of battery electric and plug-in hybrid electric vehicles, along with additional technical information, approximately three years prior to certification.

Certification Fuel

- Change the ethanol limit for LEV III certification gasoline to expand the overlap between the allowable ethanol limit and the allowable total oxygen content;

- Allow the use of federal Tier 3 certification gasoline as an alternative to both California LEV III certification gasoline for LEV III passenger cars, light-duty trucks, and medium-duty vehicles and to California certification gasoline for LEV II passenger cars, light-duty trucks, and medium-duty vehicles; and
- Allow the use of federal E85 certification fuel as an alternative to California LEV III E85 certification fuel for LEV III passenger cars, light-duty trucks, and medium-duty vehicles.

Non-Methane Organic Gas Test Procedures

- Split the “Non-Methane Organic Gas Test Procedure” into two separate test procedures to correspond with the incorporation of 40 CFR Part 1066 beginning with the 2017 model year.

Heavy-Duty Engine and Vehicle Test Procedures

- Update both the Heavy-Duty Otto-Cycle Test Procedures and the Heavy-Duty Diesel Test Procedures to incorporate revisions to the CFR on April 28, 2014;
- Change the allowable ethanol content for certification gasoline for 2020 and subsequent model year heavy-duty Otto-cycle engines and vehicles to expand the overlap between the allowable ethanol content and total oxygen content and to match the proposed changes to LEV III certification gasoline;
- Allow the use of Tier 3 certification gasoline as an alternative to California certification gasoline for heavy-duty Otto-cycle engines and vehicles; and
- Allow the use of federal E85 certification fuel as an alternative to California E85 certification fuel for heavy-duty engines and vehicles.

Environmental Performance Label

- Revise the Environmental Performance Label to include LEV III vehicles.

Hybrid Electric Vehicle Test Procedures

- Incorporate 40 CFR Part 1066 into the California test procedures.
- Reduce certification test burden for vehicle manufacturers by establishing more efficient emission test procedures for qualifying PHEVs.
- Clarify that the PHEV test procedures continue to require worst case operation mode for emission testing as originally adopted in 2008.
- Provide alternatives to meeting the state-of-charge (SOC) criterion that currently must be satisfied before a PHEV emission test is considered valid.

Objectives and Benefits of the Proposed Regulation:

The objective of this rulemaking is to incorporate various federal Tier 3 provisions to allow manufacturers to certify both California and federal vehicles using a single set of test procedures. In addition, more stringent SFTP PM standards for light- and medium-duty vehicles will reduce the health effects and premature deaths associated with these emissions. The proposed changes will also include revisions to the hybrid electric vehicle test procedures designed to reduce the test burden and simplify testing requirements for manufacturers.

ARB held a number of meetings with representatives from the automotive industry, as well as one public workshop to engage stakeholders and obtain input on the proposed changes to the regulations and test procedures. In addition, ARB staff participated in dozens of individual meetings with vehicle manufacturers to discuss the proposed changes.

**DETERMINATION OF INCONSISTENCY AND
INCOMPATIBILITY WITH EXISTING
STATE REGULATIONS**

During the process of developing the proposed regulatory action, ARB has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

**MANDATED BY FEDERAL LAW
OR REGULATIONS (if applicable)**

This regulation is not mandated by federal law or regulations.

COMPARABLE FEDERAL REGULATIONS

As mentioned above, on April 28, 2014, a Final Rulemaking was issued by U.S. EPA that established the Tier 3 regulations for light-duty vehicles, beginning in the 2017 model year (see footnote 1). These Tier 3 regulations include criteria pollutant emission standards that are similar to LEV III, updated test protocols for determining compliance with emission standards, and revisions to the hybrid electric vehicle testing requirements. While these Tier 3 regulations are similar to the LEV III regulations, minor differences will remain between the two regulations if the changes proposed in this rulemaking are adopted. These differences exist to ensure achievement of the emission benefits California needs within the state.

**AVAILABILITY OF DOCUMENTS AND
AGENCY CONTACT PERSONS**

ARB staff has prepared a Staff Report: Initial Statement of Reasons (ISOR) for the proposed regulatory action, which includes a summary of the economic and environmental impacts of the proposal. The report is titled: "Proposed Amendments to the LEV III Criteria Pollutant Requirements for Light- and Medium-Duty Vehicles, the Hybrid Electric Vehicle Test Procedures, and the Heavy-Duty Otto-Cycle and Heavy-Duty Diesel Test Procedures."

Copies of the ISOR and the full text of the proposed regulatory language, in underline and strikeout format to allow for comparison with the existing regulations, may be accessed on ARB's website listed below, or may be obtained from the Public Information Office, Air Resources Board, 1001 I Street, Visitors and Environmental Services Center, First Floor, Sacramento, California, 95814, (916) 322-2990, on September 3, 2014.

Final Statement of Reasons Availability

Upon its completion, the Final Statement of Reasons (FSOR) will be available and copies may be requested from the agency contact persons in this notice, or may be accessed on ARB's website listed below.

Agency Contact Persons

Inquiries concerning the substance of the proposed regulatory action may be directed to the designated agency contact persons, Ms. Sarah Carter at (626) 575-6845 or Mr. Paul Hughes at (626) 575-6977.

Further, the agency representative to whom nonsubstantive inquiries concerning the proposed administrative action may be directed is Amy Whiting, Regulations Coordinator, (916) 322-6533. The Board staff has compiled a record for this rulemaking action, which includes all the information upon which the proposal is based. This material is available for inspection upon request to the contact persons.

Internet Access

This notice, the ISOR and all subsequent regulatory documents, including the FSOR, when completed, are available on ARB's website for this rulemaking at <http://www.arb.ca.gov/regact/2014/leviii2014/leviii2014.htm>.

**DISCLOSURES REGARDING THE
PROPOSED REGULATION**

The determinations of the Board's Executive Officer concerning the costs or savings necessarily incurred by public agencies and private persons and businesses in reasonable compliance with the proposed regulatory action are presented below.

Fiscal Impact/Local Mandate

Pursuant to Government Code sections 11346.5(a)(5) and 11346.5(a)(6), the Executive Officer has determined that the proposed regulatory action would not create costs or savings to any State agency or in federal funding to the State, costs or mandate to any local agency or school district, whether or not reimbursable by the State pursuant to Government Code, title 2, division 4, part 7 (commencing with section 17500), or other nondiscretionary cost or savings to State or local agencies.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

The Executive Officer has made an initial determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states, or on representative private persons.

The proposed regulatory amendments would impose minimal costs on affected parties and have minimal or no economic impacts on businesses because such parties would be subject to nearly identical requirements under federal Tier 3 regulations.

Cost Impacts on Representative Private Persons or Businesses

In developing this regulatory proposal, ARB staff evaluated the potential economic impacts on representative private persons or businesses. The ARB is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Results of the Economic Impact Analysis/Assessment Prepared Pursuant to Government Code Sec. 11346.3(b)**Effect on Jobs/Businesses:**

The Executive Officer has determined that the proposed regulatory action would not affect the creation or elimination of jobs within the State of California, the creation of new businesses or elimination of existing businesses within the State of California, or the expansion of businesses currently doing business within the State of California. A detailed assessment of the economic impacts of the proposed regulatory action can be found in the Economic Impact Analysis in the ISOR.

Benefits of the Proposed Regulation:

California currently has its own regulations to control criteria pollutant emissions from passenger vehicles. Auto manufacturers do, however, demonstrate compliance with both California regulations and Federal regulations using test procedures that are substantially similar. The California test procedures incorporate sec-

tions of Part 86 of the CFR, which are modified as needed to incorporate California-specific requirements. However, U.S. EPA has recently adopted modifications to the CFR that migrate the testing requirements in Part 86 to a new Part 1066. The primary objective of the proposed amendments to the regulation is to incorporate Part 1066 into the California test procedures to enable California to retain the sections of the test procedure that currently reside in Part 86.

A summary of these benefits is provided, please refer to "Objectives and Benefits", under the Informative Digest of Proposed Action and Policy Statement Overview Pursuant to Government Code 11346.5(a)(3) discussion on page 1554.

Effect on Small Business

The Executive Officer has also determined, pursuant to California Code of Regulations, title 1, section 4, that the proposed regulatory action would not affect small businesses because small businesses are not regulated parties under these regulations.

Housing Costs

The Executive Officer has also made the initial determination that the proposed regulatory action will not have a significant effect on housing costs.

Business Reports

In accordance with Government Code sections 11346.3(c) and 11346.5(a)(11), the Executive Officer has found that the reporting requirements of the proposed regulatory action which apply to businesses are necessary for the health, safety, and welfare of the people of the State of California.

Alternatives

Before taking final action on the proposed regulatory action, the Board must determine that no reasonable alternative considered by the Board, or that has otherwise been identified and brought to the attention of the Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

Environmental Analysis

When the ACC Program was proposed in 2012, ARB prepared an environmental analysis (EA) under its certified regulatory program (California Code of Regulations, title 17, sections 60000 through 60008) to comply with the requirements of the California Environmental Quality Act (CEQA; Public Resources Code section 21080.5). The EA, included in Appendix B of the ISOR entitled Appendix B: Draft Environmental Analysis for the Advanced Clean Cars Program, dated December 7, 2011, determined the ACC Program could result in ad-

verse impacts to aesthetics, air quality, noise, biological resources, cultural resources, geology/soils, hazards/hazardous materials, hydrology/water quality, traffic and utilities; however the portion of the program specific to the LEV III regulation did not find any adverse environmental impacts. Staff has determined that no additional environmental review is required for the current proposed amendments because there are no changes that involve new significant environmental effects or a substantial increase in severity of previously identified significant effects in the prior 2011 EA. The basis for reaching this conclusion is provided in Chapter VII of the ISOR.

WRITTEN COMMENT PERIOD AND
SUBMITTAL OF COMMENTS

Interested members of the public may present comments orally or in writing at the hearing and may provide comments by postal mail or by electronic submittal before the hearing. The public comment period for this regulatory action will begin on September 5, 2014. To be considered by the Board, written comments not physically submitted at the hearing, must be submitted on or after September 5, 2014 and received **no later than 5:00 p.m. on October 20, 2014**, and must be addressed to the following:

Postal mail: Clerk of the Board, Air Resources
Board
1001 I Street,
Sacramento, California 95814

Electronic submittal: <http://www.arb.ca.gov/lispub/comm/bclist.php>

Please note that under the California Public Records Act (Gov. Code, § 6250 et seq.), your written and oral comments, attachments, and associated contact information (e.g., your address, phone, email, etc.) become part of the public record and can be released to the public upon request.

ARB requests that written and email statements on this item be filed at least 10 days prior to the hearing so that ARB staff and Board members have additional time to consider each comment. The Board encourages members of the public to bring to the attention of staff in advance of the hearing any suggestions for modification of the proposed regulatory action.

Additionally, the Board requests but does not require that persons who submit written comments to the Board reference the title of the proposal in their comments to facilitate review.

AUTHORITY AND REFERENCE

This regulatory action is proposed under the authority granted in Health and Safety Code, sections 38501, 38510, 38560, 38562, 38580, 39010, 39500, 39600, 39601, 39667, 40000, 43006, 43013, 43018, 43101, 43104, 43105, 43106, 43107, 43200, 43806, and 44036.2, and Vehicle Code sections 27156 and 28114. This action is proposed to implement, interpret, and make specific sections 38501, 38505, 38510, 38560, 38562, 39002, 39003, 39010, 39017, 39033, 39500, 39650, 39657, 39667, 39701, 43000, 43000.5, 43009, 43009.5, 43206, 43100, 43101, 43101.5, 43102, 43104, 43105, 43106, 43107, 43204, 43205, 43205.5, 43210, 43211, 43212, 43213, and 43806 Health and Safety Code.

HEARING PROCEDURES

The public hearing will be conducted in accordance with the California Administrative Procedure Act, Government Code, title 2, division 3, part 1, chapter 3.5 (commencing with section 11340).

Following the public hearing, the Board may adopt the regulatory language as originally proposed, or with non-substantial or grammatical modifications. The Board may also adopt the proposed regulatory language with other modifications if the text as modified is sufficiently related to the originally proposed text that the public was adequately placed on notice and that the regulatory language as modified could result from the proposed regulatory action; in such event, the full regulatory text, with the modifications clearly indicated, will be made available to the public, for written comment, at least 15 days before it is adopted.

The public may request a copy of the modified regulatory text from ARB's Public Information Office, Air Resources Board, 1001 I Street, Visitors and Environmental Services Center, First Floor, Sacramento, California, 95814, (916) 322-2990.

SPECIAL ACCOMMODATION REQUEST

Consistent with California Government Code Section 7296.2, special accommodation or language needs may be provided for any of the following:

- An interpreter to be available at the hearing;
- Documents made available in an alternate format or another language;
- A disability-related reasonable accommodation.

To request these special accommodations or language needs, please contact the Clerk of the Board at (916) 322-5594 or by facsimile at (916) 322-3928 as

soon as possible, but no later than 10 business days before the scheduled Board hearing. TTY/TDD/Speech to Speech users may dial 711 for the California Relay Service.

Consecuente con la sección 7296.2 del Código de Gobierno de California, una acomodación especial o necesidades lingüísticas pueden ser suministradas para cualquiera de los siguientes:

- Un intérprete que esté disponible en la audiencia
- Documentos disponibles en un formato alternativo u otro idioma
- Una acomodación razonable relacionados con una incapacidad

Para solicitar estas comodidades especiales o necesidades de otro idioma, por favor llame a la oficina del Consejo al (916) 322-5594 o envíe un fax a (916) 322-3928 lo más pronto posible, pero no menos de 10 días de trabajo antes del día programado para la audiencia del Consejo. TTY/TDD/Personas que necesiten este servicio pueden marcar el 711 para el Servicio de Re-transmisión de Mensajes de California.

TITLE 13. AIR RESOURCES BOARD

NOTICE OF PUBLIC HEARING TO CONSIDER 2014 AMENDMENTS TO THE ZERO EMISSION VEHICLE REGULATION

The Air Resources Board (ARB or Board) will conduct a public hearing at the time and place noted below to consider proposed amendments to the California Zero Emission Vehicle (ZEV) regulation.

DATE: October 23, 2014

TIME: 9:00 a.m.

PLACE: South Coast Air Quality Management District Auditorium
21865 E. Copley Drive
Diamond Bar, California 91765-4182

This item will be considered at a two-day meeting of the Board, which will commence at 9:00 a.m., October 23, 2014, and may continue at 8:30 a.m., on October 24, 2014. This item may not be considered until October 24, 2014. Please consult the agenda for the hearing, which will be available at least 10 days before October 23, 2014, to determine the day on which this item will be considered.

INFORMATIVE DIGEST OF PROPOSED ACTION AND POLICY STATEMENT OVERVIEW PURSUANT TO GOVERNMENT CODE 11346.5(a)(3)

Sections Affected: Proposed amendments to California Code of Regulations (CCR), title 13, sec-

tions 1962.1 and 1962.2; and to the following documents incorporated by reference therein: “California Exhaust Emission Standards and Test Procedures for 2009 through 2017 Model Zero-Emission Vehicles and Hybrid Electric Vehicles, in the Passenger Car, Light-Duty Truck, and Medium-Duty Vehicle Classes”, as adopted December 17, 2008, as last amended May 30, 2014, and “California Exhaust Emission Standards and Test Procedures for 2018 and Subsequent Model Zero-Emission Vehicles and Hybrid Electric Vehicles, in the Passenger Car, Light-Duty Truck, and Medium-Duty Vehicle Classes,” as adopted March 22, 2012, as last amended May 30, 2014.

Background and Effect of the Proposed Rulemaking:

As part of the 2012 Advanced Clean Car (ACC) rule-making, the Board approved amendments to the intermediate volume manufacturer (IVM) definition within Section 1900, title 13, California Code of Regulations (CCR). An IVM was previously defined as any manufacturer with California sales between 4,501 and 60,000 new light- and medium-duty vehicles. The 2012 amendments reduced the California sales upper bound to 20,000 vehicles per year beginning with the 2018 model year. The 2012 amendments concurrently changed the IVMs’ ZEV obligations from being able to meet the mandate with super clean conventional partial zero emission vehicles (PZEVs) to transitional ZEVs (TZEVs, generally plug-in hybrids). At the 2012 hearing, the Board directed staff to revisit the 20,000 vehicle threshold and the IVM ZEV obligation to determine if the provisions were appropriate for the IVM category of manufacturers.

At the October 2013 Board Hearing on minor modifications to the ZEV regulation, a number of IVMs¹ presented a proposal for changes to the ZEV regulation that would provide them with the regulatory relief they felt was necessary to allow them time to come into the advanced technology vehicle market. Their proposed changes included very small demonstration quantities of ZEVs through 2025, large credit multipliers for any ZEVs produced, travel and pooling of both ZEVs and TZEVs in ZEV states, extended service credits for cars offered for sale or extended leases, and three years to make up ZEV credit deficits. As a result of the presentation, the Board directed staff to work with the IVMs to understand their needs and propose amendments as appropriate.

Staff will now present proposed ZEV Regulation modifications to the Board that provide additional compliance flexibility to the IVMs. This flexibility is achieved by providing additional production lead time, a reduced compliance obligation, an opportunity to

¹ Jaguar Land Rover, Mazda, Mitsubishi, Subaru, and Volvo

pool compliance obligations in “Section 177” states, and additional time to make up credit deficits. The staff proposal also includes minor changes to the fast refueling definition and corrects grammatical errors.

Description of the Proposed Regulatory Action, Objectives, and Benefits:

Proposed Regulatory Action:

Staff is proposing modifications to the ZEV Regulation that provide additional compliance flexibility to IVMs working to bring advanced technology vehicles to market. A detailed discussion of the proposed amendments appears in Chapter III (Summary of Proposed Action) of the Staff Report: Initial Statement of Reasons for Rulemaking for the 2014 Modifications to the Zero Emission Vehicle Regulation. The parenthetical references are to the affected sections in title 13, CCR.

1) Modify the IVM definition to add a global revenue test (1962.2(b)(7)(A)).

In January 2012, the Board approved changes to the ZEV Regulation that modified the IVM definition within Section 1900, title 13, California Code of Regulations (CCR) to specify that, beginning with the 2018 model year, an IVM was any manufacturer with California sales between 4,501 and 20,000 new light- and medium-duty vehicles based on the average number of vehicles sold for the three, previous consecutive model years for which a manufacturer seeks certification. Concurrently, the Board directed staff to revisit the 20,000-vehicle threshold to determine if the threshold was appropriate for manufacturers in the IVM category.

Staff subsequently determined that the vehicle sales threshold, in and of itself, is not sufficiently useful in assessing a manufacturer’s ability to bring advanced technology vehicles to market. In consultation with manufacturers, we determined that a better indicator of this ability is robust global revenue in conjunction with the established manufacturer sales threshold. Accordingly, staff is proposing a global revenue threshold of 40 billion dollars, based upon the average of the three consecutive fiscal years preceding the determination. The global revenue test is only available to IVMs for the 2018 and 2019 model years (i.e., the global revenue test is phased out starting with model year 2020). Beginning in the 2020 model year, a manufacturer exceeding the 20,000 vehicle threshold will need to prepare to bring ZEVs to market per the large volume manufacturer (LVM) requirements; staff expect most IVMs will make ZEVs available for sale by the 2025 model year.

2) Provide IVMs additional production lead time (1962.2(b)(7)(A)).

The ZEV Regulation currently provides lead time, prior to requiring a ZEV model for compliance, to an IVM transitioning to LVM status. The existing regulatory language (which provides for 3 consecutive three-year sales averages once the first three-year average exceeds 20,000 vehicles) could provide an IVM as few as 3 years before that IVM would be subject to the LVM requirements. This is significantly shorter than the normal product development timeline. ARB staff is proposing to extend the lead time to 5 three-year averages commencing once the first three-year average exceeds 20,000 vehicles. This provides IVMs a minimum of 5 years and a maximum of 7 years to bring a ZEV to market. This lead time is similar to the lead time provisions established for IVMs that transitioned to LVM status prior to 2018 in ZEV regulation versions prior to the 2012 amendments.

3) Decrease the percent of ZEVs that IVMs must produce (1962.2(b)(1)(A)).

The ZEV regulation allows an IVM to meet its pre-2018 model year ZEV obligation solely with partial zero emission allowance vehicles² (PZEV). It then requires the IVM, in 2018 and subsequent model years, to begin delivering ZEVs. However in recognition of the lower number of vehicle models offered by the typical IVM, and its lesser research and development capabilities as compared to LVMs, the ZEV Regulation allows an IVM to meet its entire ZEV obligation with TZEVs.

The pre-2018 model year PZEV provisions were intended to ease the burden on IVMs in comparison to LVMs since PZEVs are much easier to market as compared to the ZEVs required under the ZEV provisions for LVMs. Unfortunately, while the intention was to decrease the burden on IVMs, the existing regulation has the unintended practical effect of establishing two hurdles for IVMs starting in 2018. First, an LVM has had several years to develop ZEV offerings and accrue credits from the placement of those ZEVs. With the ZEV regulation only requiring IVMs to produce PZEVs and considering that IVMs’ lesser revenues make it more challenging for them to develop multiple advanced technology models simultaneously, IVMs

² Typically, PZEVs are conventional gasoline, diesel, or natural gas vehicles that meet the most stringent standards for smog-forming emissions. They additionally have zero evaporative emissions and extended emission control warranties.

generally have not been able to bring forth ZEV offerings and accrue the higher credits that ZEVs offer. Second, without the research and development and economic means to concurrently develop both TZEVs and greater credit ZEVs, an IVM must plan to offer a significantly greater portion of its sales (potentially in excess of 40 percent by 2025³) as TZEVs to meet its obligation.

To address these issues, staff is proposing to adjust downward the total ZEV credit obligation for IVMs in the 2018 through 2025 model years by looking at the LVM's total percent of new car sales that are expected to be ZEVs and TZEVs. Specifically, the proposed obligation is set at a credit level equivalent to one-fifth of the LVM pure ZEV obligation plus the entire LVM optional TZEVE obligation. This results in an IVM having an advanced technology vehicle sales percentage (based on a likely compliance scenario) more closely aligned to that of the LVMs. Additionally, the proposed ZEV credit percentage requirements for IVMs may be met entirely with TZEVs.

4) Provide a pathway for IVMs to pool compliance obligations in Section 177 states (1962.2(d)(5)(E)).

Section 177 of the federal Clean Air Act⁴ allows other states to adopt California motor vehicle emission standards including the ZEV Regulation. Currently, nine states (hereinafter referred to as the Section 177 states) have adopted the California ZEV Regulation: Connecticut, Maine, Maryland, Massachusetts, New Jersey, New York, Oregon, Rhode Island, and Vermont.

In 2012, the Board adopted changes to the ZEV Regulation establishing a new optional Section 177 State compliance path. The changes allow manufacturers to place extra ZEVs in the Section 177 states one and two years prior to the 2018 model year. In exchange for early placement of these extra ZEVs, manufacturers gain the ability to pool credits across state lines within and between two regional pools⁵. They also earn a reduced TZEVE obligation.

Currently, only one IVM has a ZEV product or plans to bring a ZEV to market prior to the 2018 model year, so essentially only LVMs have been able to make use of these provisions. The IVMs have stated that they need this same ability to pool ZEV and TZEVE credits across

state lines because some of them have few dealers in some of the Section 177 States. Accordingly, staff is proposing to change the Section 177 State optional compliance path to provide additional flexibility for IVMs. Specifically, it is proposed that the IVMs may place extra ZEVs in Section 177 States in the two model years prior to the start of their LVM requirements should they transition to LVM status. However, in recognition of production timing constraints and the IVM's ability to place vehicles as a new LVM, the IVMs may take an additional two years to place these extra ZEVs. The IVMs will also be allowed to pool TZEVE credits to meet total annual percentage obligations in each Section 177 State. They will not be allowed a reduced TZEVE obligation.

5) Allow additional time to make up ZEV credit deficits (1962.2(g)(7)(A)).

Beginning in 2018, the ZEV regulation requires automakers to make up a ZEV credit deficit by the next model year. IVMs have stated that the existing one-year period does not provide sufficient time to address a potentially underperforming advanced technology vehicle model and have asked for a three-year credit recovery period consistent with the non-methane organic gas provisions within the LEV III component of the ACC rulemaking. Staff is proposing to extend the make-up period for IVMs to three years. In recognition of the fact that a longer deficit period may allow an automaker to accrue an even larger deficit, staff is also proposing two constraints. First, the three-year credit recovery period will only be made available to IVMs that have actually delivered a ZEV or TZEVE to market. IVMs that have not marketed a ZEV or TZEVE will only be provided a one-year credit recovery period. Second, automakers with a credit deficit will be required to provide ARB an action plan illustrating how the automaker will achieve compliance concurrent with their annual reporting first indicating the deficit.

Currently, a manufacturer must fulfill a ZEV credit deficit with credits earned from ZEVs. To provide additional flexibility for IVMs, staff is also proposing to allow IVMs to fulfill a ZEV credit deficit with TZEVE credits. This flexibility is consistent with existing regulatory provisions as IVMs may meet their entire ZEV credit percentage requirement with credits from TZEVEs.

6) Clarify the fast refueling definition (1962.1(d)(5)(B)).

Amendments adopted in 2001 provide that ZEVs with the ability to refuel to 95 percent of full capacity within 15 minutes are allowed to earn more credit under specific ZEV Type designations. Prior to the amendments that went into effect in July 2014, some BEVs had qualified under the fast refueling definition because

³ IVM Joint Comments Letter dated October 24, 2013 (<http://www.arb.ca.gov/lists/com-attach/8-zev2013-B2FTPFwzUGIKYAhX.pdf>).

⁴ United States Code, title 42, section 7507.

⁵ Two regional pools were created for the purpose of this provision: the West Region pool and East Region Pool. States west of the Mississippi River, excluding California, make up the West Region pool, and states east of the Mississippi River make up the East Region pool.

of their potential for battery exchanges. However, it has not been shown that battery exchanges were actually occurring on the vehicles earning credits. Accordingly, ARB amended the ZEV regulation in 2014 to require: (1) actual fast refueling events (e.g., actual battery exchanges) to qualify for such credits, and (2) manufacturers seeking to earn fast refueling credits to submit the number of fast refueling events that occur over a 12-month period for all otherwise eligible vehicles in the vehicle fleet.

Comments received before and after the October 2013 Board Hearing included concerns that vehicles placed in the latter part of a model year would not be able to count fast refueling events after the calendar year had ended. Under the scenario proposed by the manufacturers, a 2015 model year BEV placed in service on October 31, 2015 would only be able to count those fast refueling events that occurred between October 31 and December 31, 2015. This was not staff's intent, and staff is proposing to clarify that fast refueling events occurring during the initial 12-month period following the vehicle's placement in California would qualify for the fast refueling credit.

This suite of modifications to the ZEV regulation provides manufacturers greater flexibility in complying with the regulations while continuing the Board's commitment to the ZEV program requirements and advanced technology vehicles. Staff is also proposing minor grammatical corrections.

Beginning in March 2014, ARB staff conducted a series of meetings, conference calls, and a public workshop on July 14, 2014, to engage stakeholders and obtain input on the proposed regulatory amendments. These stakeholders included representatives from manufacturers, Section 177 states, and environmental advocates. The workshop was held at ARB offices in Sacramento and broadcast via webcast. The announcements and materials for this workshop were posted on ARB's website and distributed through a list serve that included over 14,500 recipients. In an effort to build consensus and minimize areas of disagreement, staff worked with the Section 177 states, environmental advocates, and manufacturers on the proposed modifications presented at the workshop.

Objective:

At the January 2012 and October 2013 public hearings, the Board directed staff to revisit the need to provide additional compliance flexibility to IVMs while still maintaining the Board's commitment to a strengthened ZEV regulation. Staff's proposal provides the IVMs with the regulatory relief deemed necessary by the Board while ensuring continued progress toward the production of advanced technology vehicles.

Benefits:

The additional flexibility provided by the proposed modifications ensures that IVMs will be able to smoothly transition to LVM status thus making the commercialization of advanced technology vehicles by IVMs and the emissions benefits that accompany them more certain. Finally, the commercialization of ZEVs (zero emission vehicles) will help achieve California's goal of long-term air quality and climate change.

DETERMINATION OF INCONSISTENCY AND INCOMPATIBILITY WITH EXISTING STATE REGULATIONS

During the process of developing the proposed regulatory action, ARB has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

This regulation is not mandated by federal law or regulations.

COMPARABLE FEDERAL REGULATIONS

This regulation does not have comparable federal regulations.

AVAILABILITY OF DOCUMENTS AND AGENCY CONTACT PERSONS

ARB staff has prepared a Staff Report: Initial Statement of Reasons (ISOR) for the proposed regulatory action, which includes a summary of the economic and environmental impacts of the proposal, and all information upon which the proposed regulation is based. The report is entitled: "Proposed 2014 Amendments to the Zero Emission Vehicle Regulation."

Copies of the ISOR and the full text of the proposed regulatory language, in underline and strikeout format to allow for comparison with the existing regulations, may be accessed on ARB's website listed below, or may be obtained from the Public Information Office, Air Resources Board, 1001 I Street, Visitors and Environmental Services Center, First Floor, Sacramento, California, 95814, (916) 322-2990, on September 2, 2014.

Final Statement of Reasons Availability

Upon its completion, the Final Statement of Reasons (FSOR) will be available and copies may be requested

from the agency contact persons in this notice, or may be accessed on ARB's website listed below.

Agency Contact Persons

Inquiries concerning the substance of the proposed regulation may be directed to the designated agency contact persons, Mark Williams, Air Pollution Specialist, (916) 327-5610 and the back-up contact person Elise Keddie, ZEV Implementation Section Manager, (916) 323-8974.

Further, the agency representative to whom non-substantive inquiries concerning the proposed administrative action may be directed is Amy Whiting, Regulations Coordinator, (916) 322-6533. The Board staff has compiled a record for this rulemaking action, which includes all the information upon which the proposal is based. This material is available for inspection upon request to the contact persons.

Internet Access

This notice, the ISOR and all subsequent regulatory documents, including the FSOR, when completed, are available on ARB's website for this rulemaking at <http://www.arb.ca.gov/regact/2014/zev2014/zev2014.htm>.

DISCLOSURES REGARDING THE PROPOSED REGULATION

The determinations of the Board's Executive Officer concerning the costs or savings necessarily incurred by public agencies and private persons and businesses in reasonable compliance with the proposed regulatory action are presented below.

Fiscal Impact/Local Mandate

Pursuant to Government Code sections 11346.5(a)(5) and 11346.5(a)(6), the Executive Officer has determined that the proposed regulatory action would not create costs or savings to any State agency or in federal funding to the State, costs or mandate to any local agency or school district, whether or not reimbursable by the State pursuant to Government Code, title 2, division 4, part 7 (commencing with section 17500), or other nondiscretionary cost or savings to State or local agencies.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

The Executive Officer has made an initial determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states, or on representative private persons.

Cost Impacts on Representative Private Persons or Businesses

In developing this regulatory proposal, ARB staff evaluated the potential economic impacts on representative private persons or businesses. The ARB is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Results of The Economic Impact Analysis/Assessment Prepared Pursuant to Government Code Sec. 11346.3(b)

Effect on Jobs/Businesses:

The Executive Officer has determined that the proposed regulatory action would not affect the creation or elimination of jobs within the State of California, the creation of new businesses or elimination of existing businesses within the State of California, or the expansion of businesses currently doing business within the State of California. A detailed assessment of the economic impacts of the proposed regulatory action can be found in the Economic Impact Analysis in the ISOR.

Benefits of the Proposed Regulation:

The objective of the proposed amendments to the regulation is to provide additional compliance flexibility to the IVMs, make minor changes to the fast refueling definition, and correct grammatical errors. Continued compliance with the ZEV Regulation will create a positive impact on emission benefits, and benefits the air quality of the state's environment.

A summary of these benefits is provided, please refer to "Objectives and Benefits", under the Informative Digest of Proposed Action and Policy Statement Overview Pursuant to Government Code 11346.5(a)(3) discussion on page 1558.

Effect on Small Business

The Executive Officer has also determined, pursuant to California Code of Regulations, title 1, section 4, that the proposed regulatory action would not affect small businesses because small businesses are not regulated parties under these regulations.

Housing Costs

The Executive Officer has also made the initial determination that the proposed regulatory action will not have a significant effect on housing costs.

Business Reports

In accordance with Government Code sections 11346.3(c) and 11346.5(a)(11), the Executive Officer has found that the reporting requirements of the proposed regulatory action, which apply to businesses, are necessary for the health, safety, and welfare of the people of the State of California.

Alternatives

Before taking final action on the proposed regulatory action, the Board must determine that no reasonable al-

ternative considered by the Board, or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

Environmental Analysis

When the ACC Program was proposed in 2012, ARB prepared an environmental analysis (EA) under its certified regulatory program (California Code of Regulations, title 17, sections 60000 through 60008) to comply with the requirements of the California Environmental Quality Act (CEQA; Public Resources Code section 21080.5). The EA, included in Appendix B of the ISOR entitled Appendix B: Draft Environmental Analysis for the Advanced Clean Cars Program, dated December 7, 2011, determined the ACC Program could result in adverse impacts to aesthetics, air quality, noise, biological resources, cultural resources, geology/soils, hazards/hazardous materials, hydrology/water quality, traffic and utilities. Staff has determined that no additional environmental review is required for the current proposed amendments because there are no changes that involve new significant environmental effects or a substantial increase in severity of previously identified significant effects in the prior 2011 EA. The basis for reaching this conclusion is provided in Chapter IV of the ISOR.

WRITTEN COMMENT PERIOD AND SUBMITTAL OF COMMENTS

Interested members of the public may present comments orally or in writing at the hearing and may provide comments by postal mail or by electronic submittal before the hearing. The public comment period for this regulatory action will begin on September 5, 2014. To be considered by the Board, written comments not physically submitted at the hearing, must be submitted on or after September 5, 2014, and received **no later than 5:00 p.m. on October 20, 2014**, and must be addressed to the following:

Postal mail: Clerk of the Board, Air Resources Board
1001 I Street,
Sacramento, California 95814

Electronic submittal: <http://www.arb.ca.gov/lispub/comm/bclist.php>

Please note that under the California Public Records Act (Gov. Code, § 6250 et seq.), your written and oral comments, attachments, and associated contact information (e.g., your address, phone, email, etc.) be-

come part of the public record and can be released to the public upon request.

ARB requests that written and email statements on this item be filed at least 10 days prior to the hearing so that ARB staff and Board members have additional time to consider each comment. The Board encourages members of the public to bring to the attention of staff in advance of the hearing any suggestions for modification of the proposed regulatory action.

Additionally, the Board requests but does not require that persons who submit written comments to the Board reference the title of the proposal in their comments to facilitate review.

AUTHORITY AND REFERENCE

This regulatory action is proposed under the authority granted in Health and Safety Code, sections 39600, 39601, 43013, 43018, 43101, 43104 and 43105. This action is proposed to implement, interpret, and make specific sections 38562, 39002, 39003, 39667, 43000, 43009.5, 43013, 43018, 43018.5, 43100, 43101, 43101.5, 43102, 43104, 43105, 43106, 43204, 43205, 43205.5 and 43206 of the Health and Safety Code.

HEARING PROCEDURES

The public hearing will be conducted in accordance with the California Administrative Procedure Act, Government Code, title 2, division 3, part 1, chapter 3.5 (commencing with section 11340).

Following the public hearing, the Board may adopt the regulatory language as originally proposed, or with non-substantial or grammatical modifications. The Board may also adopt the proposed regulatory language with other modifications if the text as modified is sufficiently related to the originally proposed text that the public was adequately placed on notice and that the regulatory language as modified could result from the proposed regulatory action; in such event, the full regulatory text, with the modifications clearly indicated, will be made available to the public, for written comment, at least 15 days before it is adopted.

The public may request a copy of the modified regulatory text from ARB’s Public Information Office, Air Resources Board, 1001 I Street, Visitors and Environmental Services Center, First Floor, Sacramento, California, 95814, (916) 322-2990.

SPECIAL ACCOMMODATION REQUEST

Consistent with California Government Code Section 7296.2, special accommodation or language needs may be provided for any of the following:

- An interpreter to be available at the hearing;

- Documents made available in an alternate format or another language;
- A disability-related reasonable accommodation.

To request these special accommodations or language needs, please contact the Clerk of the Board at (916) 322-5594 or by facsimile at (916) 322-3928 as soon as possible, but no later than 10 business days before the scheduled Board hearing. TTY/TDD/Speech to Speech users may dial 711 for the California Relay Service.

Consecuente con la sección 7296.2 del Código de Gobierno de California, una acomodación especial o necesidades lingüísticas pueden ser suministradas para cualquiera de los siguientes:

- Un intérprete que esté disponible en la audiencia
- Documentos disponibles en un formato alterno u otro idioma
- Una acomodación razonable relacionados con una incapacidad

Para solicitar estas comodidades especiales o necesidades de otro idioma, por favor llame a la oficina del Consejo al (916) 322-5594 o envíe un fax a (916) 322-3928 lo más pronto posible, pero no menos de 10 días de trabajo antes del día programado para la audiencia del Consejo. TTY/TDD/Personas que necesiten este servicio pueden marcar el 711 para el Servicio de Re-transmisión de Mensajes de California.

TITLE 13. CALIFORNIA HIGHWAY PATROL

TITLE 13 CALIFORNIA CODE OF REGULATIONS,
DIVISION 2, CHAPTER 6
AMEND ARTICLE 2.7, SECTION 1159

ROUTES FOR THE THROUGH TRANSPORTATION OF HIGHWAY ROUTE CONTROLLED QUANTITY SHIPMENTS OF RADIOACTIVE MATERIALS (CHP-R-12-03)

The California Highway Patrol (CHP) proposes to amend Title 13 of the California Code of Regulations related to designated routes for the transportation of Highway Route Controlled Quantity (HRCQ) shipments of Radioactive Materials (RAM).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Pursuant to Section 33000 of the California Vehicle Code (CVC), Division 14.5, the CHP shall adopt regulations specifying the routes to be used in the Through

Transportation of HRCQ RAM. Proposed changes are developed to update the designated routes by enhancing the clarity and consistency of the narrative listing of routes with the route map; therefore, the updated regulations will present a better network of designated routes and clearer maps of designated routes for HRCQ RAM transporters to plan their shipment routes in advance. Consistent with the legislative intent and the purpose of existing regulations, the proposed amendment will continue to provide benefits which include a non-monetary benefit to the protection and safety of public health for residents and workers, and the protection and safety to the environment by providing a regulatory basis for enforcement efforts.

During the process of developing these regulations and amendments, the CHP has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. For the proposed regulation amendments, the CHP conducted consultation and received concurrence from the State Fire Marshall, California Department of Public Health, and the California Department of Transportation.

PUBLIC COMMENTS

Any interested person may submit written comments on the proposed action via facsimile at (916) 322-3154, by electronic mail to cvsregs@chp.ca.gov, or by writing to:

California Highway Patrol
Commercial Vehicle Section
Attention: Dr. Tian-Ting Shih
P.O. Box 942898
Sacramento, CA 94298-0001

Written comments will be accepted until 5:00 p.m., on October 20, 2014.

PUBLIC HEARINGS

No public hearing has been scheduled. If any person desires a public hearing, a written request must be received by the CHP, Commercial Vehicle Section (CVS) no later than 15 days prior to the close of the written comment period.

AVAILABILITY OF INFORMATION

The CHP has available for public review an initial statement of reasons for the proposed regulatory action, the information upon which this action is based (the rulemaking file), and the proposed regulation text in strikeout and underline format. Requests to review or receive copies of this information should be directed to

the CHP at the foregoing address, by facsimile at (916) 322-3154, or by calling the CHP CVS at (916) 843-3400. Facsimile requests for information should include the following information: The title of the rule-making package, requester's name, proper mailing address (including city, state, and zip code), and a daytime telephone number, in case the information is incomplete or illegible.

The rulemaking file is available for inspection at the CHP, CVS, 601 B North Seventh Street, Sacramento, CA 95811. Interested parties are advised to call for an appointment.

All documents regarding the proposed action are available through the CHP Website at www.chp.ca.gov/regulations. Any person desiring to obtain a copy of the adopted text and a final statement of reasons may request them at the above noted address. Copies will be posted on the CHP Web site.

CONTACT PERSON

Any inquiries concerning the written materials pertaining to the proposed regulations or the substance of the proposed regulations should be directed to Dr. Tian-Ting Shih. The back up contact person for these inquiries is Sergeant Josh Clements, CHP, CVS at (916) 843-3400.

ADOPTION OF PROPOSED REGULATIONS

After consideration of public comments, the CHP may adopt the proposal substantially as set forth without further notice. If the proposal is modified prior to adoption and the change is not solely grammatical or is non-substantive in nature, the full text of the resulting regulation, with the changes clearly indicated, will be made available to the public for at least 15 days prior to the date of adoption.

FISCAL AND RESULTS OF ECONOMIC IMPACT

The CHP has made an initial determination that this proposed regulatory action: (1) will have no effect on housing costs; (2) will not impose any new mandate upon local agencies or school districts; (3) will involve no non-discretionary or reimbursable costs or savings to any local agency, school district, state agency, or federal funding to the state; (4) will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand businesses in the State of California; (5) will continue to provide benefits which include a nonmonetary benefit to the protection and safety of public health for residents

and workers, and the protection and safety to the environment by providing a regulatory basis for enforcement efforts as they relate to safety compliance ratings; and (6) will not have a significant statewide adverse economic impact directly affecting businesses including the ability of California businesses to compete with businesses in other states. The regulated community is encouraged to respond during the comment period of this regulatory process if significant impacts are identified.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

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

EFFECT ON SMALL BUSINESSES

The CHP has determined that the proposed regulatory action will not affect small businesses. The action is intended to clarify and update the routes for highway commercial vehicles transporting HRCQ RAM. As a result, no small business will be affected by the update.

ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the CHP must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to the attention of the CHP, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The CHP invites interested parties to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

AUTHORITY

This regulatory action is being taken pursuant to Section 33000, CVC.

REFERENCE

This action implements, interprets, or makes specific Section 33000, CVC.

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in

the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 20, 2014.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the DCA Headquarters Building Two, 1747 North Market Blvd Room 186, Sacramento, CA 95834, on November 4, 2014, at 10:30 a.m.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005, 4057 and 4127 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4036, 4037, 4040, 4051, 4052, 4057, 4076, 4081, 4127, 4127.7, 4169, 4301, and 4332 of the Business and Professions Code, as well as Section 18944 of the California Health and Safety Code, the Board of Pharmacy is proposing to amend Articles 4.5 and 7 and add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy (“Board”) proposes to amend Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8 and Sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, and 1751.10, as well as add Article 7.5 and Sections 1751.9, 1752, 1753, and 1754 of Division 17 of Title 16 of the California Code of Regulations (“CCR”) for the purpose of amending the board’s regulations specific to the compounding of drug products as part of the board’s efforts to strengthen the regulation and enforcement of pharmacies that compound sterile drug products and as a result of Senate Bill (SB) 294 (Emmerson, Statutes of 2013, Chapter 565.), as specified below.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California.

SB 294 commencing July 1, 2014, expands these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. SB 294 also specifies requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. SB 294 requires the board to adopt regulations to implement these provisions, and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary, as specified.

As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Included as part of the federal Drug Quality and Security Act (HR 3204) that became law on November 27, 2013, are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by “outsourcing facilities.” The federal law sets forth voluntary requirements for licensure and enforcement of these entities. However, California’s law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with the board and comply with California requirements as sterile compounding pharmacies. The FDA may also require or encourage licensure as an outsourcing facility.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence. Compounding pharmacies also make drugs, but they are limited to producing small amounts in response to a

specific patient’s prescription, or to creating a small supply for an identifiable patient population to ensure continuity of treatment. The state-by-state approach to regulating compounding organizations yields inconsistent standards and varying levels of enforcement on an industry that ships dangerous drugs across state lines.

Additionally, there are compounding professional standards that are used across the nation known as the United States Pharmacopeia and The National Formulary (USP–NF). USP–NF is a book of public pharmacopeial standards. It contains standards for (chemical and biological drug substances, dosage forms, and compounded preparations), excipients, medical devices, and dietary supplements. USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF. The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP–NF to avoid possible charges of adulteration and misbranding.

In October 2012, the New England Compounding Center (NECC), based in Massachusetts, shipped contaminated product throughout the country, including California, that resulted in the death of more than 60 people and 750 patients becoming ill from the tainted injections. NECC’s compounding facility had obvious ongoing safety violations, but continued to operate and ship products despite employee whistleblower complaints to management. The compounding facility failed to maintain its clean room. The air intake for the clean room was contaminated and shared with the neighboring furniture recycling facility, and employees discovered mold on various work and storage surfaces several times per year. Yet, NECC remained accredited and was licensed to ship sterile compounded injectable products into California.

Because the board had to rely on third-party accreditation, the board did not have the opportunity or authority to inspect NECC or prevent NECC from shipping products into California until patients in other states had already been harmed.

NECC is not the only compounding pharmacy to have recently caused significant patient harm. In June 2012, a sterile injectable pharmacy located in Florida shipped contaminated product into California which resulted in significant patient harm, including blindness in some cases. Again, the board was only able to take action after patient harm had already occurred.

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California’s compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013–January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

During the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

After reviewing and considering the written and oral comments received, board staff recommended to the board to withdraw the current rulemaking file originally noticed November 29, 2013, and provide general guidance from the sterile compounding workgroup to develop new updated language based on substantive comments received by the board and notice the revised language as a new rulemaking. At the April 2014 Board meeting, the board agreed with the recommendation. The board submitted a “Decision Not to Proceed” with the rulemaking file and was published in the California Notice Register on May 9, 2014.

The board’s sterile compounding workgroup continued to work with stakeholders provide for revised language that maintained the board’s as well as addressed stakeholders’ concerns. The board’s proposal demonstrates the board’s desire to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out compounding in general (including sterile injectable).

PROBLEM/BENEFITS STATEMENT APPLYING TO ALL SECTIONS

The problem addressed is to ensure current compounding regulations reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). The board’s proposal also addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 37 <797> and reducing such discrepancy for the compounding profession who are compounding drug products in California and ship-

ping into California so as to ensure the safety of all consumers receiving compounded drugs in California. This is a real benefit to the people of the State of California particularly when the protection of public health and safety, worker safety, or the environment is involved.

Documents Incorporated by Reference: Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia — National Formulary (USP37 — NF 32 through 2nd Supplement) (37th Revision, Effective December 1, 2014).

Amend 16 CCR §1735

Existing regulations at 16 CCR §1735 specify requirements related to the compounding of drug products in licensed pharmacies.

The purpose of the board’s proposal makes the following changes:

- Subdivision (4) adds “compounded” to clarify the type of drug preparation.
- Subdivision (4) deletes “product” and replaces with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (4)(b) adds a comma between rectal and topical to clarify the separate routes of administration.
- Subdivision (4)(b) adds “the sole act of” to clarify tablet splitting is not included in the compounding definition.
- Subdivision (4)(b) adds “or crushing, capsule opening,” to clarify these routes are not included in the compounding definition.
- Subdivision (c) deletes “product” replaces with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (d) deletes “injectable” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation.

Amend 16 CCR §1735.1

Existing regulations at 16 CCR § 1735.1 specify requirements related to the compounding of drug products, to include definitions of terms used throughout Articles 4.5 and 7.

The purpose of the board’s proposal will add the following definitions or amend the following subdivisions as listed below.

- Subdivision (a) adds a definition of “anteroom” for purposes of compounding drug products. The definition clarifies and specifies “anteroom” means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the buffer area and maintains air flows from clean to dirty areas.
- Subdivision (b) adds a definition of “batch” for purposes of compounding drug products. The definition clarifies and specifies “batch” means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.
- Subdivision (c) adds a definition of “beyond use date” for purposes of compounding drug products. The definition clarifies and specifies “beyond use date” means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.
- Subdivision (d) adds a definition of “buffer area” for purposes of compounding drug products. The definition clarifies and specifies “buffer area” means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.
- Subdivision (e) adds a definition of “bulk drug” for purposes of compounding drug products. The definition clarifies and specifies “bulk drug” means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.
- Subdivision (f) adds a definition of “cleanroom” for purposes of compounding drug products. The definition clarifies and specifies “cleanroom” (which may also be referred to as a buffer area)

means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding.

- Subdivision (g) adds a definition of “controlled cold temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled cold temperature” means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).
- Subdivision (h) adds a definition of “controlled freezer temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled freezer temperature” means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F).
- Subdivision (i) adds a definition of “controlled room temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled room temperature” means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).
- Subdivision (j) renumbers previous subdivision (a) as subdivision (j).
- Subdivision (k) adds a definition of “first air” for purposes of compounding drug products. The definition clarifies and specifies “first air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
- Subdivision (l) adds a definition of “gloved fingertip sampling” for purposes of compounding drug products. The definition clarifies and specifies “gloved fingertip sampling” means a process where, compounding personnel lightly press each fingertip and thumb onto appropriate growth media, that are then incubated at a temperature and for a time period conducive to

multiplication of microorganisms, and then examined for growth of microorganisms.

- Subdivision (m) renumbers previous subdivision (b) as subdivision (m). Subdivision (m) amends the definition of “integrity” for the purposes of compounding drug products. The definition clarifies and specifies “integrity” means that all aspects of quality including sterility, packaging, chemical stability and potency, handling, and transport and storage are maintained throughout the drug preparation process, and until the beyond use date provided on the label. The revised definition removes “retention of potency” and changes “expiration” to “beyond use” as well as changes “noted” to “provided.”
- Subdivision (n) adds a definition of “media-fill test” for purposes of compounding drug products. The definition clarifies and specifies “media-fill test” means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.
- Subdivision (o) adds a definition of “parenteral” for purposes of compounding drug products. The definition clarifies and specifies “parenteral” means a sterile preparation of drugs for injection or implantation through one or more layers of skin.
- Subdivision (p) adds a definition of “personal protective equipment” for purposes of compounding drug products. The definition clarifies and specifies “personal protective equipment” means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
- Subdivision (q) renumbers previous subdivision (c) as subdivision (q). Subdivision (q) amends the definition of “potency” for the purposes of compounding drug products. The definition clarifies and specifies “potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement, Effective December 1, 2014) of the labeled amount by adding “(or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement, Effective December 1, 2014).”

- Subdivision (r) adds a definition of “preparation” for purposes of compounding drug products. The definition clarifies and specifies “preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.
- Subdivision (s) adds a definition of “prescriber’s office” or “prescriber office” for purposes of compounding drug products. The definition clarifies and specifies “prescriber’s office” or “prescriber office” means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.
- Subdivision (t) adds a definition of “Primary Engineering Control (PEC)” for purposes of compounding drug products. The definition clarifies and specifies “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.
- Subdivision (u) adds a definition of “process validation” for purposes of compounding drug products. The definition clarifies and specifies “process validation” means demonstrating that when a process is operated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.
- Subdivision (v) adds a definition of “product” for purposes of compounding drug products. The definition clarifies and specifies “product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (w) renumbers previous subdivision (d) as subdivision (w). Subdivision (w) amends the definition of “quality” for the purposes of compounding drug products. The definition clarifies and specifies “quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label by adding “and inactive” to the definition.
- Subdivision (x) adds a definition of “segregated compounding area” for purposes of compounding drug products. The definition clarifies and specifies “segregated compounding area” means a designated space where a device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aseptic isolators, is located within either a demarcated area (at least three foot perimeter) or room. Such area shall

contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within at least three feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations.

- Subdivision (y) adds a definition of “smoke test” for purposes of compounding drug products. The definition clarifies and specifies “smoke test” means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.
- Subdivision (z) renumbers previous subdivision (e) as subdivision (z). Subdivision (z) amends the definition of “strength” for the purposes of compounding drug products. The definition clarifies and specifies “strength” means amount of active ingredient per unit of a compounded drug preparation. The word “preparation” replaced the word “product” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

These changes are necessary is to ensure consistency in for all compounded drug products with sterile ingredients and not limit it to only those sterile drug products from one or more non-sterile ingredients.

Amend 16 CCR §1735.2

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements; self-assessment.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deletes “product” twice and replaces with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deletes “product” replaces with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (c) deletes “as used in” and replaces with “furnished to a prescriber for office use by the prescriber as authorized by” to clarify the application of “reasonable quantity” in accordance with Business and Professions Code section 4052. The word “subdivision” is added to clarify the regulation refers to subdivision (a)(1) of the Section 4052 of the Business and Professions Code.
- Subdivision (c) deletes “product” and replaces with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c)(1) further clarifies subdivision (c) and deletes “or application to patients in the prescriber’s office, or for distribution of not more than” and “to the prescriber’s patients, as estimated by the prescriber” and adds “ordered and paid for by the prescriber, using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is”; “either office”; and “or furnishing of.”
- Subdivision (c)(2) further clarifies subdivision (c) by adding “is delivered to the prescriber office and signed for by the prescriber; and.”
- Subdivision (c)(3) further clarifies subdivision (c) by adding “is sufficient for administration or application to patients solely in the prescriber’s office, or for furnishing of not more than a 72-hour supply solely to the prescriber’s own patients seen as part of regular treatment in the prescriber’s office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and.”
- Subdivision (c)(4) further clarifies subdivision (c) by adding “(4)” to “is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and.”
- Subdivision (c)(5) further clarifies subdivision (c) by renumbering subdivision (c)(3) to subdivision (c)(5) and replacing “product” with “preparation; and” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c)(6) further clarifies subdivision (c) by adding “does not exceed an amount the pharmacy can reasonably and safely compound.”
- Subdivision (d) adds the following language to specify when a pharmacy or pharmacist shall not compound a drug preparation by adding, “No pharmacy or pharmacist shall compound a drug preparation that:
 - (1) is classified by the FDA as demonstrably difficult to compound;
 - (2) appears on a FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or
 - (3) is a copy or essentially a copy of one or more drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.”
- Subdivision (e) renumbers previous subdivision (d) as subdivision (e) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e)(3) deletes “Expiration dating requirements.” and replaces with “The rationale or reference source for determining the maximum allowable beyond use date for this preparation.” to specify the requirement for determining the maximum allowable beyond use date.
- Subdivision (e)(5) deletes “Process and/or procedure” and replaces with “Specific compounding steps” to clarify the requirement for identifying what is used to prepare the drug from a master formula.
- Subdivision (f) renumbers previous subdivision (e) as subdivision (f) and replaces twice “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (g) renumbers previous subdivision (f) as subdivision (g) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (h) renumbers previous subdivision (g) as subdivision (h) and deletes the “l” in the word “compendial” making word “compendia” for accuracy.
- Subdivision (i) renumbers previous subdivision (h) as subdivision (i) and replaces “product(s)” with “preparation(s)” four times and adds “, stored, transported, or administration begun.” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. “An expiration” is changed to “A beyond use” and to clarify the date representing the date beyond which it is used.
- Subdivision (j) renumbers previous subdivision (i) as subdivision (j) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (k) renumbers previous subdivision (j) as subdivision (k) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The reference “(Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.)” is replaced with “as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations” to better specify the reference. Deletes “injectable” twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. “Date” is added to specify a self-assessment shall be completed within 30 days of the start date of a new pharmacist-in-charge and “or change of location” is added to specify a self-assessment shall be completed within 30 days of a change of location for the pharmacy.
- Subdivision (l) adds the following language to specify requirements for ingredients that are received without a supplier’s expiration date, “Packages of ingredients that lack a supplier’s expiration date are subject to the following limitations:
 - (1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy unless either appropriate documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and
 - (2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity.”
- California Code of Regulations sections 1735, 1735.1, 1735.8, and 1751.1–1751.8 are added to the References cited to ensure compliance with the Administrative Procedure Act.

The necessity of these changes is to make specific and further clarify the requirements for compounding limitations as well as self-assessment requirements.

Amend 16 CCR §1735.3

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board’s proposal will change the section’s title from “Records of Compounded Drug Products” to “Recordkeeping for Compounded Drug Preparations” to delineate the records are to be made and kept for compounded drug preparations. This change is necessary to clarify the board’s intentions with regard to recordkeeping regulations and addresses the problem of ensuring the board’s licensees understand the intent of the regulation.

Existing regulations at 16 CCR §1735.3 specify recordkeeping for compounded drug preparations.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “the” is also deleted to correct grammar.
- Subdivision (a)(2) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(3) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “the” was replaced with “any” and the words “who compounded the” was replaced with “engaged in compounding the” to correct grammar.
- Subdivision (a)(4) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(5) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(6) replaces “products” with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code” was moved for ease of readability. The reference “Chapter 797 of the United States Pharmacopeia — National Formulary (USP–NF) (35th Revision, Effective May 1, 2012)” was updated to the current reference of “Redispensed CSPs’ found in Chapter 797 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014).”
- Subdivision (a)(7) adds a hyphen to “pharmacy–assigned” to correct grammar. It also replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(8) deletes “expiration” and replaces with “beyond use” to specify the requirement for determining the maximum allowable beyond use date and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(9) adds the word “final” to specify the final quantity or amount. The subdivision also replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “for dispensing” is also added to the subdivision to clarify the requirement for which the final quantity or amount of drug preparation was compounded.
- Subdivision (a)(10) is added to include “Storage for the drug preparation” as a requirement for recordkeeping.
- Subdivision (c) is reorganized to add “Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other c” and the “C” is deleted to the first sentence to require FDA register suppliers be used. The word “and” is inserted between “substance” and “drug” products while “, and components” is deleted to specify the requirements. The word “products” is replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “, whenever possible,” is added; “reliable” is deleted; and “FDA–registered” qualifier is added to specify requirements for suppliers. In the second sentence, the words “any available” is deleted requiring certificate of purity or analysis for chemicals. The word “and” is added

to include certificate of purity for both chemicals and bulk drug substances. The words “, drug products, and components” are deleted for redundancy. The sentence “Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.” is deleted and the sentence “Certificates of purity or analysis are to be matched to the product received.” is added requiring certificates of purity or analysis to be matched to the product received.

- Subdivision (d) is enhanced to add the sentence “If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).” providing the requirement for electronic records maintenance.

The necessity of these changes in 16 CCR §1735.3 is required to update the recordkeeping for compounded drug preparation requirements.

Amend 16 CCR §1735.4

Existing regulations at 16 CCR §1735.4 specify requirements for labeling of compounded drug products. The purpose of the board’s proposal will change the section’s title from “Labeling of Compounded Drug Products” to “Labeling of Compounded Drug Preparations” to delineate the labeling requirements. This change is necessary to clarify the board’s intentions with regard to labeling requirements in regulations for compounded drug preparations. The board’s proposal addressed the problem of ensuring the board’s licensees understand the intent of the regulation.

Existing regulations at 16 CCR §1735.4 specify labeling for compounded drug preparations.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) replaces “products” with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “the name of the compounding pharmacy and dispensing pharmacy, if different,” is added to specify the name(s) of the pharmacies required to be on the label of a compounded drug

preparation. The word “expiration” is deleted and replaced with “beyond use” to specify the requirement for determining the maximum allowable beyond use date.

The necessity of these changes in 16 CCR §1735.4 is required to update the labeling for compounded drug preparation requirements.

Amend 16 CCR §1735.5

Existing regulations at 16 CCR §1735.5 specify compounding policies and procedures.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) adds the sentence “The pharmacy shall follow its policies and procedures. Failure to follow these policies and procedures shall constitute grounds for disciplinary action.” to ensure pharmacies are required to adhere to their own policies and procedures.
- Subdivision (b) adds the phrase “and such review shall be documented” to ensure that reviews to policies and procedures are completed and noted as such.
- Subdivision (c) adds a colon to the end of the text in the subdivision.
- Subdivision (c)(2) adds the requirement of “Evidence that staff have been educated and trained on all policies and procedures.” to ensure compounding personnel are trained in accordance with policies and procedures.
- Subdivision (c)(3) renumbers previous subdivision (2) as subdivision (3) and deletes the phrase “Documentation of a” and replaces it with “A written” to clarify the requirement for a plan of recall. The word “product” is replaced with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “of a compounded drug product” is deleted and the sentence “All affected doses can be accounted for as part of the recall.” was added to further clarify the plan of recall requirement.
- Subdivision (c)(4) renumbers previous subdivision (3) as subdivision (4).
- Subdivision (c)(5) is added to include “The procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.” thereby providing further clarification on procedures.

- Subdivision (c)(6) renumbers previous subdivision (4) as subdivision (6) and adds the phrase “appropriate to compound drug preparations” as well as deleting “test” and replacing it with “validate” to further clarify documentation of methodology. The word “product” is replaced with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c)(7) renumbers previous subdivision (5) as subdivision (7) and the word “expiration” is deleted and replaced with “beyond use” to specify the requirement for determining the maximum allowable beyond use date. The word “product” is replaced with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivisions (c)(8), (9), (10) and (11) were added to further clarify requirements for compounding policies and procedures.
 - (8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
 - (9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
 - (10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures.
 - (11) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations.
- Business and Professions Code section 4301 is added to the References Cited to ensure compliance with the Administrative Procedure Act. The word “and” is deleted and replaced later in the citation for accuracy.

The necessity of these changes in 16 CCR §1735.5 is required to update the compounding policies and procedures requirements.

Amend 16 CCR §1735.6

Existing regulations at 16 CCR §1735.6 specify compounding facilities and equipment.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deletes the word “products” and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deletes the word “products” and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) adds the phrase “that weighs, measures, or transfers ingredients” to specify what equipment this subdivision applies. The word “products” is deleted and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “, per manufacturer’s specifications,” is added to require pharmacy personnel to ensure the manufacturer’s specifications are included.

The necessity of these changes in 16 CCR §1735.6 is required to update the compounding facilities and equipment for compounded drug preparation requirements.

Amend 16 CCR §1735.7

Existing regulations at 16 CCR §1735.7 specify training of compounding staff requirements.

The purpose of the board’s proposal makes the following changes:

- Subdivision (c) deletes the word “product” and replaces it with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

The necessity of these changes in 16 CCR §1735.7 is required to update the training of compounding staff for compounded drug preparation requirements.

Amend 16 CCR §1735.8

Existing regulations at 16 CCR §1735.8 specify compounding quality assurance requirements.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deletes the word “products” and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) deletes the word “products” twice and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (d) deletes the word “product” and replaces it with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e) is added to require “The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations, including for preparations furnished to patient care areas.” to ensure policies and procedures address out-of-range temperature variations.

The necessity of these changes in 16 CCR §1735.8 is required to update the compounding quality assurance requirements.

Amend 16 CCR §1751

Existing regulations at 16 CCR §1751 specify requirements for sterile injectable compounding. The purpose of the board’s proposal will change the section’s title from “Sterile Injectable Compounding” to “Sterile Compounding” to delineate the sterile compounding requirements. This change is necessary to clarify the board’s intentions with regard to sterile compounding requirements in regulations and addressed the problem of ensuring the board’s licensees understand the intent of the regulation.

Existing regulations at 16 CCR §1751 specify sterile compounding requirements.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deletes “injectable” twice referring to sterile injectable compounding and to

reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (a) also deletes “products” and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (b) deletes “injectable” twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes “products” and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. This subdivision also deletes “designated” and adds “compounding” and “designated.” The word “drug” is added before preparation. These changes clarify the compounding area designated for the preparation of sterile drug preparations. The following phrase and sentence is added to enhance the understanding of the compounding area designated for the preparation of sterile drug preparations, “preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The buffer area, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.” The phrase “which shall meet the following standards:” was deleted and replaced

with “The environments within the pharmacy shall meet the following standards:” for clarity.

- Subdivision (b)(1)–(4) was deleted and (4) was written as the current subdivision (b)(1) to state, “Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years.” This ensured the requirements for certification of ISO environments are done at least every six months in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations.
- Subdivision (b)(2) renumbers previous subdivision (5) as subdivision (2). The following sentence was deleted, “The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.” The word “injectable” was deleted once and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes “products” and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b)(3) renumbers previous subdivision (6) as subdivision (3). The following sentence was added to specify the location of sinks and drains, “Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante–area.”
- Subdivision (b)(4) renumbers previous subdivision (7) as subdivision (4). In subdivision (b)(4), a comma was added and the “/or” was removed. Inserted after the comma is the phrase “where appropriate, a.” A comma was inserted after the word “freezer.” The phrase “or freezing”

was added to the last sentence. These changes clarified the refrigerator/freezer requirements.

- Subdivision (c) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes “products” and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Sections 1735, 1735.1–1735.8, and 1751.1–1751.8 of Title 16, Division 17, of the California Code of Regulations is added to the References Cited to ensure compliance with the Administrative Procedures Act.

The necessity of these changes in 16 CCR §1751 is required to update the sterile compounding; compounding area; and self–assessment requirements for sterile compounded drug preparations.

Amend 16 CCR §1751.1

Existing regulations at 16 CCR §1751.1 specify requirements for sterile injectable recordkeeping requirements. The purpose of the board’s proposal will change the section’s title from “Sterile Injectable Recordkeeping Requirements” to “Sterile Compounding Recordkeeping Requirements” to delineate the sterile compounding recordkeeping requirements. This change is necessary to clarify the board’s intentions with regard to sterile compounding requirements in regulations and addressed the problem of ensuring the board’s licensees understand the intent of the regulation.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) is deleted in its entirety, “Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.” This subdivision text is added as the new subdivision (b).

- Subdivision (b) is renumbered to (a) with the deletion of reference to the former subdivision (a) by deleting the following phrase “and subdivision (a).” The phrase “compounded drug” is added while “products” is deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Additionally, “compounded from one or more non-sterile ingredients” is deleted to further clarify this requirement.
 - Subdivision (a)(1) deleted “product” and replaced it with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
 - Subdivision (a)(2) was added to include results of gloved fingertip testing assessments, “Results of hand hygiene and garbing assessment with integrated gloved fingertip testing.”
 - Subdivision (a)(3) was added to include aseptic technique assessments, “Results of assessments of personnel for aseptic techniques including results of media fill tests and gloved fingertip testing performed in association with media fill testing.”
 - Subdivision (a)(4) was added to include viable volumetric air and surface sampling, “Results of viable volumetric air and surface sampling.”
 - Subdivision (a)(5) was renumbered from (2) as the current (5) to include additional documentation of refrigerator and freezer temperature requirements. “Daily documentation of room” was added to the beginning of the sentence with the “R” for refrigerator being changed to a lowercase “r” and a comma being added after refrigerator. The phrase was added to the end of the sentence and included the following temperatures, “appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:
 - (A) Controlled room temperature.
 - (B) Controlled cold temperature.
 - (C) Controlled freezer temperature.”
 The period after the colon was deleted for accuracy.
 - Subdivision (a)(6) was renumbered from (3) as the current (6) and added an “s” to “certification” to include all certifications for the sterile compounding environment.
 - Subdivision (a)(7) was added to include requirements for air pressure differentials and air velocity documentation, “Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators.”
 - Subdivision (a)(8) was renumbered from (4) as the current (8).
 - Subdivision (a)(9) was renumbered from (5) as the current (9) to add the requirement of “Logs or other documentation” of inspections for expired or recalled pharmaceutical products or raw ingredients for better patient health and safety. The “I” from “Inspection” was changed to “i” and an “s” was added to “inspection” for accuracy.
 - Subdivision (a)(10) was renumbered from (6) as the current (10).
 - Subdivision (b) was moved from the previous subdivision (a) and stated as, “Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a prescriber.”
 - Subdivision (c) added the following sentence to address requirements for electronically stored data, “If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).”
- The necessity of these changes in 16 CCR §1751.1 is required to update the sterile compounding recordkeeping requirements.
- Amend 16 CCR §1751.2*
- Existing regulations at 16 CCR §1751.2 specify sterile injectable labeling requirements. The purpose of the board’s proposal will change the section’s title from “Sterile Injectable Labeling Requirements” to “Sterile Compounding Labeling Requirements” to delineate the sterile compounding labeling requirements. This change is necessary to clarify the board’s intentions with regard to sterile compounding requirements in regulations and address the problem of ensuring the board’s licensees understand the intent of the regulation.
- The purpose of the board’s proposal makes the following changes:

- “California Code of Regulations” was added to ensure the correct citation for section 1735.4. The word “injectable” was deleted twice and replaced twice with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted twice and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. A few minor grammatical changes were made in changing “for” to “to” and “of” to “by.”
- Subdivision (b) deleted the “s” on concentrations. Subdivision (b) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded

in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (d) deleted the word “cytotoxic” and replaced it with “hazardous.” The phrase “Chemotherapy — Dispose of Properly” was deleted and moved to the end of the sentence with the addition of “, if applicable.” The word “Cytotoxic” was deleted and replaced with “Hazardous.” The word “or” was deleted.

The necessity of these changes in 16 CCR §1751.2 is required to update the sterile compounding labeling requirements for compounded drug preparation requirements.

Amend 16 CCR §1751.3

Existing regulations at 16 CCR §1751.3 specify requirements for sterile injectable policies and procedures. The purpose of the board’s proposal will change the section’s title from “Sterile Injectable Policies and Procedures” to “Sterile Compounding Policies and Procedures” to delineate the sterile compounding policy and procedures requirements.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deleted the word “injectable” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation and to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(1) deleted the words “injectable compounds” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.) and replaced with “drug preparations.” California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the

eye or inhalation. The word “compounds” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (a)(2) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “product” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a)(3) added “Proper use of” and deleted the “E” replacing it with an “e” to further clarify the proper use of equipment and supplies.
- Subdivision (a)(4) added “all aspects of” as well as deleted “injectable” replacing it with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “product” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The subdivision (a)(4) is extended to include specific requirements for training and knowledge competency of staff, “including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of

controlled compounding areas and proper aseptic technique.”

- Subdivision (a)(5) was added to include hand hygiene and garbing, “Hand hygiene and garbing.”
- Subdivision (a)(6) was added to include cleaning and maintenance, “Cleaning and maintenance of ISO environments and segregated compounding areas.”
- Subdivision (a)(7) was added to include environmental sampling plan and procedures, “An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.”
- Subdivision (a)(8) was added to include manufacturer’s purge times, “For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer’s recommended purge time.”
- Subdivision (a)(9) was added to include media fill testing procedures, “Media fill testing procedure.”
- Subdivision (a)(10) was added to include stability and beyond use dating, “Compounded sterile drug preparation stability and beyond use dating.”
- Subdivision (a)(11) was added to include final quality checks, “Visual inspection and other final quality checks of sterile drug preparations.”
- Subdivision (a)(12) was renumbered from (5) as the current (12). The phrase “, compounding and disposal of” was added while “cytotoxic” was replaced with “hazardous” to allow for more descriptive requirement for handling of hazardous agents.
- Subdivision (a)(13) was renumbered from (6) as the current (13).
- Subdivision (a)(14) was renumbered from (7) as the current (14).
- Subdivision (c) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted twice and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where

- product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “cytotoxic” was deleted and replaced with the word “hazardous” as this is a more commonly used nomenclature.
- Subdivision (d) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “from one or more non-sterile ingredients” was deleted to require written policies and procedures for drug preparations from one non-sterile ingredient.
 - Subdivision (d)(2) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
 - Subdivision (d)(3)(A) added “Orientation, training, and” and the “C” was changed to “c” as well as added “of compounding personnel.” This clarifies requirements for competency evaluation.
 - Subdivision (d)(3)(D) added “Media fill testing and” while deleting “P” and replacing it with “p” for process validation to clarify the requirement of process validation.
 - Subdivision (d)(3)(E) deleted “Personnel access and movement of materials into and near the controlled area” and added “Conduct of personnel in controlled areas and aseptic technique overview.” to further define personnel conduct.
 - Subdivision (d)(3)(F) deleted “environmental control devices” and replaced with the new definition of “PEC.” “Critical” was deleted and replaced with “direct compounding” and “manipulation of sterile products” was deleted and replaced with “compounding of sterile drug preparations.” The parenthetical “(e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).” was deleted.
 - Subdivision (d)(3)(G) deleted “Regular” and replaced with “Daily and monthly” to cleaning and added “and disinfection” to increase the requirements for cleaning and disinfecting. The phrase “and the alteration of disinfectants” was deleted and replaced with the correct citation of “as specified in California Code of Regulations section 1751.4.” The sentence regarding exemptions was deleted, “Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.”
 - Subdivision (d)(3)(H) deleted the sentence, “Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.” and replaced it with “Non-viable particle testing” to further define the testing requirement.
 - Subdivision (d)(3)(I) deleted the sentence, “For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.” and replaced it with “Viable air sampling.” to further specify the viable air sampling.
 - Subdivision (d)(3)(J) deleted “Sterilization” and replaced it with “Surface sampling” to further define the requirements for surface sampling.
 - Subdivision (d)(3)(K) deleted “End-product evaluation and testing.” and replaced with “Airflow considerations and pressure differential monitoring.” to further specify airflow differential monitoring.
 - Subdivision (d)(3)(L) added requirements for temperature and humidity monitoring, “Temperature and humidity monitoring in compounding and controlled storage areas.”

- Subdivision (d)(3)(M) added requirements for facility management, “Facility management including certification and prevention maintenance of controlled environments and related equipment.”
- Subdivision (d)(3)(N) added requirements for sampling, “Gloved fingertip sampling.”
- Subdivision (d)(3)(O) added requirements for stability and assignment of beyond use dating, “Compounded sterile product stability and assignment of beyond use dating.”
- Subdivision (d)(3)(P) added requirements for automated compounding devices, “Use of automated compounding devices (if applicable).”
- Subdivision (d)(3)(Q) added requirements for hazardous drug compounding, “Hazardous drug compounding (if applicable).
 - (i) Hazardous drug employee training and safety program.
 - (ii) Hazardous drug handling, storage, labeling and transport.
 - (iii) Hazardous drug compounding techniques.
 - (iv) Hazardous drug spill, deactivation and waste management.”
- Subdivision (d)(3)(R) added requirements for sterile solutions, “Preparing sterile solutions from nonsterile components (if applicable).”
- Subdivision (d)(3)(S) added requirements for hand hygiene and garbing, “Hand hygiene and garbing.”
- Subdivision (d)(4)(A) added requirements for disposal and sanitation, “Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.”
- Subdivision (d)(4)(B) added requirements for sterile batch compounding, “For sterile batch compounding:
 - (i) use of master formulas and compounding work sheets;
 - (ii) appropriate documentation; and
 - (iii) appropriate sterility and bacterial endotoxin testing.”
- Subdivision (d)(4)(C) added requirements for non-sterile to sterile compounding, “For non-sterile to sterile compounding:
 - (i) Sterilization methods
 - (ii) End-product evaluation and testing.”
- Subdivision (d)(4)(D) added requirements for action levels for colony-forming units, “Action levels for colony-forming units (CFUs) detected during viable surface testing, glove fingertip and volumetric air sampling.”

The necessity of these changes in 16 CCR §1751.3 is required to update the sterile compounding policies and procedures for compounded drug preparation requirements.

Amend 16 CCR §1751.4

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile injectable compounding. The purpose of the board’s proposal will change the section’s title from “Facility and Equipment Standards for Sterile Injectable Compounding” to “Facility and Equipment Standards for Sterile Compounding” to delineate the facility and equipment standards for sterile compounding.

Existing regulations at 16 CCR §1751.4 specify facility and equipment standards for sterile compounding.

The purpose of the board’s proposal makes the following changes:

 - Subdivision (a) deleted the word “injectable” twice and replaced with “drug” once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “product(s)” was deleted twice and replaced with “preparation(s)” twice to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
 - Subdivision (b) added “compounding of” and removed “preparation of” to further clarify when this subdivision applied. Subdivision (b) also deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug

products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “areas” was added and “area or cleanroom” was deleted prior to the addition of “for compounding” to further clarify the area in which this subdivision applies.

- Subdivision (c) added the word “areas” and “area or cleanroom” was deleted prior to the addition of “for compounding” to further clarify the area in which this subdivision applies.
- Subdivision (d) added the following to clarify where cleaning and disinfecting should take place, “Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:
 - (1) at the beginning of each shift;
 - (2) before and after each batch;
 - (3) after each spill; and
 - (4) when surface contamination is known or suspected.”
- Subdivision (e) was renumbered from (d) as the current (e). The sentence, “Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.” was deleted and the following inserted to be more specific in what must be disinfected, “Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.”
- Subdivision (f) was renumbered from (e) as the current (f). The following was added to clarify requirements for pharmacies preparing sterile compounded preparations requiring the use of a PEC that provides ISO Class 5 or better, “Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls

shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets the following criteria:

- (1) particle counts sampled approximately 6–12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- (2) not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
- (3) recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators or compounding aseptic containment isolators that do not meet the requirements as outlined in this subdivision and are not located within an ISO Class 7 buffer area may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.”

- Subdivision (g) deleted “parenteral cytotoxic” and replaced with “sterile hazardous” to specify the agents required to adhere to Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations. The words “laminar air flow hood” were replaced with negative pressure PEC” and “hood” was replaced with “negative pressure PEC” for clarification of the equipment. Certification was clarified when “annually” was deleted and “every six months” replaced it. The reference of “the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised

May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications." was deleted and replaced with "CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012)" to update the requirement reference. The sentence "Certification records must be retained for at least 3 years." was deleted and these sentences were added to further define the requirement for the subdivision, "Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover, facemask, beard cover (if applicable), polypropylen or low shedding gown that closes in the back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation."

- Subdivision (h) was added to provide requirements if compounding aseptic isolators are used, "If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again."
- Subdivision (i) was added to provide clarity on viable surface sampling and volumetric air sampling requirements, "Viable surface sampling shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months for low and medium risk-level compounding and weekly for high-risk compounding. Viable surface and volumetric air sampling shall be performed by a qualified individual who is familiar with the methods and

procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management."

- Subdivision (j) was added to provide clarity for the working environment of compounding personnel, "The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH)."

The necessity of these changes in 16 CCR §1751.4 are required to update the facility and equipment standards for sterile compounding requirements.

Amend 16 CCR §1751.5

Existing regulations at 16 CCR §1751.5 specify requirements for sterile injectable compounding attire. The purpose of the board's proposal will change the section's title from "Sterile Injectable Compounding Attire" to "Sterile Compounding Attire" to delineate the sterile compounding attire requirements.

Existing regulations at 16 CCR §1751.5 specify compounding policies and procedures.

The purpose of the board's proposal makes the following changes:

- Subdivision (a) is deleted and later rephrased in the new subdivision (b) to further define the requirements for appropriate attire when preparing hazardous agents.
- Subdivision (a) was renumbered from (b) as the current (a). The word "drug" was added and "products" was replaced with "preparations" as well as "from one or more non-sterile ingredients" was deleted to clarify when compounding sterile drug preparation standards must be met.
- Subdivision (a)(1) replaced the words "Cleanroom garb" with "Personal protective equipment" as well as "low" changed to "non" and "coverall" changed to "gown" to describe the type of attire required during sterile compounding. The phrases "facial hair covers (if applicable)," and " , unless the compounding aseptic isolator or compounding aseptic containment isolator

manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing are not required” were added to further describe the requirements as well as allow for the manufacturer’s specifications of compounding aseptic isolator or compounding aseptic containment isolator.

- Subdivision (a)(2) deleted “Cleanroom garb” and replaced with “Personal protective equipment” as well as replaced “outside the designated area” with “in an ante-area or immediately outside the segregated compounding area” to further clarify what must be donned and removed when preparing sterile compounding.
- Subdivision (a)(3) added the following sentences to further clarify the order in which personal protective equipment must be donned, “Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.”
- Subdivision (a)(4) was renumbered from (a)(3) as the current (a)(4) and added “Compounding personnel shall not wear.” The “h” was changed to “H” and the word “and” was changed to “or” while the phrase “must be eliminated” was deleted. All changes were made to specify who should not wear jewelry during compounding.
- Subdivision (a)(4) was deleted for duplication.
- Subdivision (a)(5) was added in lieu of Subdivision (a)(4) by striking, “Gloves made of low-shedding materials are required” and adding, “Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or buffer area. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.” to further specify the

requirements for sterile gloves to be worn during sterile compounding.

- Subdivision (a)(6) was added to specify personnel who are not allowed to participate in sterile compounding when the following applies, “Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the compounding areas until their conditions are remedied.”
- Subdivision (c) was deleted as previous subdivisions (a) and (b) were altered and subdivision (c) no longer applied.
- Subdivision (b) was added to specify attire to be required while preparing hazardous agents as, “When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).”

The necessity of these changes in 16 CCR §1751.5 is required to update the sterile compounding attire for compounded drug preparation requirements.

Amend 16 CCR §1751.6

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile injectable compounding staff, patient, and caregiver for sterile injectable compounding. The purpose of the board’s proposal will change the section’s title from “Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.” to “Sterile Compounding Consultation; Training of Sterile Compounding Staff.” to further clarify requirements on sterile compounding consultation and training of staff.

Existing regulations at 16 CCR §1751.6 specify sterile compounding consultation and training of sterile compounding staff.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) added the phrase, “, storage, handling, and disposal” to further clarify direction that should be provided to the patient and/or caregiver about instructions for taking sterile compounded drugs. The subdivision also deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of

injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (b) deleted the phrase “be responsible to” and added “that” to further clarify the pharmacist-in-charge’s responsibilities for training of compounding staff. The subdivision also deleted the word “injectable” twice and replaced with “drug” once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “shall” was deleted as it was redundant. The word “products” was deleted twice and replaced with “preparations” twice to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “cytotoxic” was deleted twice and replaced with “hazardous” twice to be more specific in the requirements of specific agents.
- Subdivision (d) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (e) deleted the phrase “products from one or more non-sterile ingredients” and replaced it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e)(1)(C) deleted the word “product” and replaced with the word “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e)(1)(E) added the phrase “using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the selected manipulations” to further specify the requirements for aseptic procedures.
- Subdivision (e)(1)(F) added “hand hygiene” to further specify the requirements for proper techniques.
- Subdivision (e)(1)(G) added the “t” to the word “the” as it was previously left out and corrects the spelling.
- Subdivision (e)(1)(H) added the words “of the” and “and” and deleted “used in” to clarify the requirement for cleaning, sanitizing, and maintaining the equipment and the controlled area.
- Subdivision (e)(1)(I) added “for compounding sterile drug preparations from one or more non-sterile ingredients” to further specify the sterilization technique requirement.
- Subdivision (e)(2) deleted the phrase “assigned to the controlled area” and replaced with the phrase “engaged in sterile compounding” as well as added the phrase “at least” to clarify the requirement for practical skills training in aseptic technique and aseptic area practices.

The necessity of these changes in 16 CCR §1751.6 is required to update the sterile compounding consultation and training of sterile compounding staff requirements.

Amend 16 CCR §1751.7

Existing regulations at 16 CCR §1751.7 specify requirements for sterile injectable compounding quality assurance and process validation. The purpose of the

board’s proposal will change the section’s title from “Sterile Injectable Compounding Quality Assurance and Process Validation.” to “Sterile Compounding Quality Assurance and Process Validation.” to further clarify requirements on sterile compounding quality assurance and process validation. Existing regulations at 16 CCR §1751.7 specify sterile compounding quality assurance and process validation.

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deleted the word “injectable” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The words “Quality Assurance Program” were changed to “quality assurance program” to correct the grammar.
- Subdivision (a)(1) added the words “Procedures for” in the beginning of the sentence; changed the “C” to “c” in cleaning; deleted the words “parenteral medicine” and added the word “sterile” to further specify the procedures for cleaning and sanitizing the sterile preparation area.
- Subdivision (a)(2) deleted in its entirety.
- Subdivision (a)(2) was renumbered from (a)(3) as the current (a)(2).
- Subdivision (a)(3) was renumbered from (a)(4) as the current (a)(3). Subdivision (a)(3) deleted “Written justification of” and replaced with “Documentation justifying” to specify the requirement for documentation justifying the chosen beyond use dates. The word “expiration” was replaced with “beyond use” to specify the use of beyond use instead of expiration date. Subdivision (a)(3) also deleted the word “injectable” and added the word “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a

sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (b) deleted the word “injectable” three times and added the word “drug” twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted three times and replaced with “preparations” three times to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “demonstrate competency by successfully performing aseptic media fill tests” replaced “complete a validation process on technique” to specify the completion of a successful aseptic media fill test. The following was deleted as this is captured in identifying the aseptic media fill test, “The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare.” The following was added to indicate the level of complexity of the required media fill testing process, “The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount of volume transferred during the compounding process.” This sentence was added to provide qualifications for a successful media test, “Media

used must have demonstrated the ability to support and promote growth.” The word “medium” was corrected to state “media” for correct grammar. The phrase “in a manner consistent with the manufacturer’s recommendations” was added to incorporate inclusion of manufacturer’s recommendations into the qualifications for successful media testing. The words “employee’s” and “and documented” were added as well as “media fill testing” replaced “validation process” to further clarify procedures when microbial growth was found in an employee’s sterile preparation process. The phrase “for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients” was added to specify competency revalidation for sterile to sterile compounding and non-sterile to sterile compounding. The word “is” was changed to “are” to correct the grammar.

- Subdivision (c) was added to specify and clarify what procedures are included in the initial competency evaluation, “All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.”
- Subdivision (d) was added to specify and clarify the components and time specific elements of re-evaluation, “Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.”
- Subdivision (e) was renumbered from (c) as the current (e). Subdivision (e) deleted the word “injectable” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted once and replaced with “preparations”

once to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “shall be subject to documented end product testing for sterility” was replaced with “that are exposed longer than 12 hours at 2 to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014),” specifies requirements for sterility testing. The words “testing for” were added before “pyrogens” and “in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference,” was added after “pyrogens” to specify that testing is required and to what standard the testing must be. The words “before dispensing” were added to clarify the testing for pyrogens must occur prior to dispensing. This sentence was added to further indicate when end product testing shall apply, “This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.” The following was added to clarify parameters for dispensing prior to receipt of the results of the testing, “In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy’s policies and procedures that includes:

- (1) Prior to dispensing:
 - (A) Notifying the prescriber of the inability to conduct testing;
 - (B) Suggesting an available alternative product to the prescriber; and
 - (C) Securing the prescriber’s written consent to dispense.

- (2) And subsequent to dispensing:
 - (A) Daily observation of the incubating test specimens; and
 - (B) Immediate recall of the dispensed compounded sterile preparations when there is any evidence of microbial or pyrogen growth in the test specimens. Any such dispensing shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.”

- Subdivision (d) was deleted as it was redundant.

The necessity of these changes in 16 CCR §1751.7 is required to update the sterile compounding quality assurance and process validation requirements.

Amend 16 CCR §1751.8

Existing regulations at 16 CCR §1751.8 was added as “Beyond Use Dating for Sterile Compounded Drug Preparations” to specify beyond use dating requirements. The necessity of these changes in 16 CCR §1751.8 are required to update the sterile compounding quality assurance and process validation requirements. The regulation that previously held 16 CCR §1751.8 was changed to 16 CCR §1751.10.

The purpose of the board’s proposal makes the following changes to add the following section as 16 CCR §1751.8:

“1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation.

- (a) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations
 - (1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices; and
 - (2) the compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

- (3) compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.

- (b) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

- (1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
- (2) the compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- (3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature.

- (c) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the

sterile compounded drug preparation lacks effective antimicrobial preservatives, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature.

For the purposes of this paragraph, “non–sterile” includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.

- (d) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations
 - (1) entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and
 - (2) the compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer’s original containers; and
 - (3) the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia — National Formulary (USP37–NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.
- (e) Where the sterile compounded drug preparation was compounded

- (1) using or containing hazardous drugs or components; and
- (2) in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non–negative pressure room) the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.
- (f) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled “for immediate use only” and administration shall begin no later than one hour following the start of the compounding process. Unless the “immediate use” preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one–hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an “immediate use” preparation.

Such “immediate use” preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

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

The necessity of these changes in 16 CCR §1751.8 is required to add the beyond use dating for sterile compounded drug preparation requirements.

Add 16 CCR §1751.9

Existing regulations at 16 CCR §1751.9 was added as “Single–Dose and Multi–Dose Containers; Limitations on Use” to specify single–dose and multi–dose containers and limitations on use requirements. The necessity of these changes in 16 CCR §1751.9 are required to add the single–dose and multi–dose containers and limitations on use requirements.

The purpose of the board’s proposal makes the following changes to add the following section as 16 CCR §1751.9:

“1751.9 Single–Dose and Multi–Dose Containers; Limitations on Use

- (a) Single–dose ampules are for immediate use only, and once opened shall not be stored for any time period.
- (b) Unless otherwise specified by the manufacturer, any single–dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents discarded within the following time limit, depending on the environment:
 - (1) When needle–punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;
 - (2) When needle–punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.
- (c) Unless otherwise specified by the manufacturer, a multi–dose container stored according to the manufacturer’s specifications shall be used in its entirety or its remaining contents discarded within twenty eight (28) days from initial opening or puncture. Any multi–dose container not stored according to the manufacturer’s specifications shall be discarded immediately upon identification of such condition.

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

The necessity of these changes in 16 CCR §1751.9 is required to add the single–dose and multi–dose containers and limitations on use requirements.

Renumber 16 CCR §1751.8 to §1751.10

Existing regulations at 16 CCR §1751.8 specify sterile injectable compounding reference materials. 16 CCR §1751.8 was renumbered to 16 CCR §1751.10 and changed from “Sterile Injectable Compounding Reference Materials” to “Sterile Compounding Reference Materials.” The word “injectable” was deleted from the title referring to sterile injectable compound-

ing and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation.

The purpose of the board’s proposal makes the following changes:

- The word “injectable” was deleted twice and the word “drug” was added once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July 1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted twice and replaced with “preparations” two times to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

The necessity of these changes in 16 CCR §1751.10 is required to update the sterile compounding reference materials requirements.

Article 7.5 Furnishing for Home Administration

Article 7.5 Furnishing for Home Administration was added as the remaining sections pertained to furnishing for home administration and not sterile compounding.

- *Renumber 16 CCR §1751.10 to 16 CCR §1752*
- *Renumber 16 CCR §1751.11 to 16 CCR §1753*
- *Renumbered 16 CCR §1753 deleted “and” from the Authority Cited section as this was a duplicate and was removed to correct the grammar.*
- *Renumber 16 CCR §1751.12 to 16 CCR §1754*

The necessity of these changes in 16 CCR Article 7.5 is required to remove them from the Article 7 pertaining to Sterile Compounding as they are not related to the topic. The problem addressed is to ensure accuracy in the regulations in that the article titles reflect the content of the article. This is a real benefit to the people of the State of California particularly when the protection of public health and safety, worker safety, or the environment is involved as pharmacists and the people working in the industry will be able to better identify code sections based on the naming convention.

After conducting a review of regulations that are related to or would affect this area, the board has determined that the regulatory proposal is not inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None.

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Effect on Housing Costs: None.

Local Mandate: None.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice and are consistent with compounding industry standards.

The proposed amendments to Articles 4.5 and 7 are intended to protect the people of California by ensuring consumers receiving compounded drug products that have been compounded in accordance with the highest safety standards. Additionally, the board understands that compounding in California and throughout the nation is compounded in accordance with USP standards. The board is establishing and incorporating these standards into California regulation. As a result, there may be cost to implement these regulations but the board does not anticipate a statewide adverse economic impact directly affecting businesses. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant. Article 7.5 is separated from Article 7 based on the content of the sections.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs businesses or the expansion of businesses in the State of California.

Small Businesses: The board’s proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are “small businesses” as defined in Government Code Section 11342.610.

Cost Impact on Representative Private Person or Business: The board understands that compounding in California and throughout the nation is compounded in accordance with USP standards. In the event a pharmacy compounding or shipping into California is not compounding in accordance with standards, the cost impacts a business could incur in becoming compliant with the proposed action are reasonable and outlined in the Economic Impact Assessment in the Underlying Data for the Initial Statement of Reasons. This determination is based on the board’s understanding of compounding in California and the nation.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The proposed amendments to Articles 4.5 and 7 are intended to protect the people of California by ensuring consumers receiving compounded drug products have been compounded in accordance with the highest safety standards. However, the board does not have any information indicating that the proposed amendments will in and of themselves have any effect on the (1) creation or elimination of jobs within the State of California, (2) creation of new businesses or the elimination of existing businesses within the State of California, or (3) expansion of businesses currently doing business within the State of California. The board does not have any information indicating the adoption of proposed amendments to Articles 4.5 and 7 would actually have a positive effect on the creation of jobs and new businesses within California and the expansion of businesses currently doing business in California. Consideration by the board as to whether the benefit to the consumers of California outweighs any negative effect on affected businesses is not anticipated to eliminate jobs or existing businesses. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice and are consistent with compounding industry standards. The addition of Article 7.5 provides for ease of finding sections related to furnishing drugs for home administration.

Creation or Elimination of Jobs within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Creation of New Businesses within California: The Board of Pharmacy has determined that this regulatory

proposal will not have a significant impact on the creation of new businesses in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Elimination of Existing Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the elimination of existing businesses in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Expansion of Businesses Currently Doing Business within the State: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the expansion of businesses currently doing business in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: The board's proposal demonstrates the board's anticipated benefit to ensure the health and welfare of California Residents, Worker Safety, and the State's environment to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out sterile and non-sterile compounding.

Occupations/Businesses Impacted: The Board of Pharmacy has made an initial determination that this regulatory proposal will impact pharmacies and specialty sterile compounding pharmacies. As of July 2014, the board had approximately 7,500 pharmacies (sites) with current licenses issued by the board. Of those 7,500 pharmacies, the board issued approximately 989 specialty sterile compounding permits.

Reporting Requirements: None.

Comparable Federal Regulations:

Included as part of the federal Drug Quality and Security Act (HR 3204) that became law on November 27, 2013, are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by "outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities. However, California's law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that is compounding sterile products for California residents

or practitioners to possess licensure with the board and comply with California requirements as sterile compounding pharmacies. The FDA may also require or encourage licensure as an outsourcing facility.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence. Compounding pharmacies also make drugs, but they are limited to producing small amounts in response to a specific patient's prescription, or to create a small supply for an identifiable patient population to ensure continuity of treatment. The state-by-state approach to regulating compounding organizations yields inconsistent standards and varying levels of enforcement on an industry that ships dangerous drugs across state lines.

Additionally, there are compounding professional standards that are used across the nation known as the United States Pharmacopeia and The National Formulary (USP-NF). USP-NF is a book of public pharmacopeial standards. It contains standards for (chemical and biological drug substances, dosage forms, and compounded preparations), excipients, medical devices, and dietary supplements. USP-NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF. The U.S. Federal Food, Drug, and Cosmetics Act designates the USP-NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP-NF to avoid possible charges of adulteration and misbranding.

Benefits: Business and Professions Code section 4005 states that "the board may adopt rules and regulations. . . pertaining to the practice of pharmacy. . . ." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The board's proposal demonstrates the board's anticipated benefit to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out sterile and non-sterile compounding.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

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

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rule-making action may be addressed to:

Name: Carolyn Klein
 Address: 1625 N. Market Blvd., N219
 Sacramento, CA 95834
 Telephone No.: (916) 574-7913
 Fax No.: (916) 574-8618
 E-Mail
 Address: Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
 Address: 1625 N. Market Blvd., N219
 Sacramento, CA 95834
 Telephone No.: (916) 574-7910
 Fax No.: (916) 574-8618
 E-Mail
 Address: Anne.Sodergren@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.

TITLE 17. DEPARTMENT OF PUBLIC HEALTH

**Title 17, California Code of Regulations
 California Biobank Program, DPH-09-020E**

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) has adopted the regulations described in this notice on an emergency basis. Health & Safety Code (HSC) section 124977(d)(1) provides that, for the purpose of the Administrative Procedure Act, the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or, general welfare. These regulations are now in effect and this notice of proposed rulemaking commences a rulemaking to make the regulations permanent.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public comment period and will hold a public hearing (pursuant to HSC section 124977(d)(1), 120 days from effective date of May 20, 2014, OAL Emergency Filing No. 2014-0515-04EFP), during which time, any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

PUBLIC HEARING

At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed

action described in the Informative Digest. The Department requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date and Time: September 17, 2014 at 10:00 a.m.

Place: 1500 Capitol Avenue,
Hearing Room 167,
Sacramento, CA 95814

Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of hearing location.

For individuals with disabilities, the Department will provide assistive services such as sign–language interpretation, real–time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write or call: Linda M. Cortez, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899–7377, phone (916) 440–7807, email at linda.cortez@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations no later than **5:00 p.m. on October 20, 2014**, which is the close of the written comment period. Comments received after this date will not be considered timely. Comments must be submitted as follows:

1. By email to: regulations@cdph.ca.gov. Please place the regulation package identifier “DPH–09–020E” in the subject line;
2. By fax transmission to: (916) 440–5747;
3. By postal service to: California Department of Public Health, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899–7377;
4. Hand–delivered to: Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, DPH–09–002E, author’s name and mailing address.

AUTHORITY AND REFERENCE

The Department is proposing to adopt the regulation sections identified under the authority provided in Sections 124977, 124991, 125002, 131050, 131051,

131052 and 131200 of the Health and Safety Code. The regulations implement, interpret and make specific sections 102175, 102465, 124975–124996, 125000, 125001, 125050, and 125119.5 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The purpose of these proposed regulations is to implement Assembly Bill (AB) 2599 (Stats. 2008, chapter 680). Health and Safety Code (HSC) Section 125002(e), requires that regulations be adopted that specify the protocols and conditions under which requests for biospecimens for research will be approved and released. The standards in these proposed regulations are limited to the release of biospecimens and/or data to approved researchers. Existing Department regulations do not address the provisions specified in AB 2599.

The Department proposes to adopt Group 6–Biobank Program, Articles 1 through 5, Sections 6550 through 6557.3, into Title 17 of the California Code of Regulations (CCR), Division 1, Chapter 4, Subchapter 9. Requirements specified in this Group will regulate the dissemination of biospecimens to Department approved researchers for the purpose of biomedical research. They set forth a request process, reasons for denial, and a fee structure for biospecimens, related data, data linkage and processing and additional related services. Requests include biospecimen retrieval, re–inventory and shipping as well as data requests in association with the biospecimens, which includes data processing, data linkage, data entry, and related data management.

Policy Statement Overview

Problem Statement:

The Department must establish guidelines for invoicing, charging and collecting fees from approved researchers that are in an amount that is necessary to cover expenses associated with research requests and to make these resources available to approved researchers. The Governor signed into law, AB 2599 which requires the Department to implement, interpret, or make specific enacted provisions to regulations that specify the protocols and conditions under which requests for biospecimens and/or data will be approved and released to researchers.

Objectives:

The broad objectives of this proposed regulatory action are to:

- Provide guidelines for invoicing, charging and collecting fees, in an amount that will cover expenses associated with research requests.

- Specify the protocols and conditions under which requests for research will be approved and released.
- Specify the protocols and conditions for biospecimen retrieval, re-inventory, and shipping.

Benefits:

Anticipated benefits from this proposed regulatory action are:

- Approved researchers will be allowed to use biospecimens and /or data for the development of diagnosis and treatment of disorders.
- Establish a uniform system for releasing biospecimens and/or data to approved researchers.
- Provide specific guidance to approved researchers as to the procedures and costs associated with the release of biospecimens and/or data from the Department.

The nonmonetary benefits to the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government of releasing biospecimens and/or data to approved researchers is impossible to determine, but they have the potential to be significant in terms of the possible advances in the diagnosis and treatment of diseases. Early diagnosis and successful treatment of disease may result in a very significant increase in the financial wellbeing, health and welfare of the people of California.

**EVALUATION AS TO WHETHER THE
PROPOSED REGULATIONS ARE
INCONSISTENT OR INCOMPATIBLE WITH
EXISTING STATE REGULATIONS**

The Department evaluated this proposal as to whether the regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to implementation of the California Biobank Program. An internet search of other state agency regulations was also performed and it was determined that no other state regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that the regulations are not inconsistent or incompatible with existing state regulations.

**MANDATED BY FEDERAL LAW
OR REGULATIONS**

Not applicable.

FORMS INCORPORATED BY REFERENCE

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

REPORTING REQUIREMENT

None.

LOCAL MANDATE

The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

FISCAL IMPACT ESTIMATE

A. COST OR SAVINGS TO ANY STATE AGENCY:

None.

B. COST TO ANY LOCAL AGENCY OR SCHOOL DISTRICT:

The Departmental costs resulting from the provision of certain biospecimens and/or related data and services, to approved researchers, and resulting from evaluating and approving researchers' requests for such biospecimens and/or data, as authorized under the proposed regulations, are estimated to be \$1,913,190.00.00 per year. These costs will be covered by the fees which the Department will collect from the researchers under the authority of the proposed regulations.

C. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED UPON LOCAL AGENCIES:

None.

D. COST OR SAVINGS IN FEDERAL FUNDING TO THE STATE:

None.

**COST IMPACT ON REPRESENTATIVE
PERSON OR BUSINESS**

The Department has determined that only those universities, research foundations, biotech companies, and non-profit organizations who choose to request and pay fees for biospecimens/and or data will be impacted. The cost will be determined by the type and quantity of bios-

specimens and/or data that the approved researcher requests.

The Department has determined that there will be no costs for individuals.

HOUSING COSTS

The Department has determined that the regulations will not have an impact on housing costs.

EFFECT ON SMALL BUSINESS

The Department has determined that only those small businesses that choose to make a request and pay fees for biospecimens and/or data will be impacted. The cost will be determined by the type and quantity of biospecimens and/or data that the approved researcher requests.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS INCLUDING THE ABILITY TO COMPETE

The Department has made an initial determination that the regulatory action will not have significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. There are no private companies at this time that have access to the number and types of biospecimens and associated data that are contained within the California Biobank Program. Thus, there will be no significant adverse economic impact on California businesses.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

There are no other businesses in the State of California that can provide biospecimens and/or data to researchers. Hence, the Department has determined that the regulations will not significantly affect the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. The regulations would benefit the health and welfare of California residents, worker safety, and the state's environment by allowing for possible advances in the diagnosis and treatment of diseases.

ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Robin Cooley, California Biobank Program Coordinator, at (510) 412-1500. In the absence of Ms. Cooley, please contact the back-up person, Linda M. Cortez, Office of Regulations, at (916) 440-7807.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-09-020E.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7807 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.

TITLE 17. DEPARTMENT OF PUBLIC HEALTH

**Title 17, California Code of Regulations
Prenatal Screening Fee Increase, DPH-14-001E**

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) has amended the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulation permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written comment period and will hold a public hearing, during which time, any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

PUBLIC HEARING

At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The Department requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date and Time: October 23, 2014,
2:00 p.m. – 4:00 p.m.

Place: 1500 Capitol Ave.,
Hearing Room 167,
Sacramento, CA 95814

Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of hearing location.

For individuals with disabilities, the Department shall provide upon request assistive services such as

sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write or call Laurel Prior, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, phone (916) 440-7673, email to Laurel.Prior@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations by **5:00 p.m. on October 20, 2014**, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Comments must be submitted as follows:

1. By email to regulations@cdph.ca.gov. Please place the regulation identifier "DPH-14-001E" in the subject line;
2. By fax transmission to: (916) 440-5747;
3. By postal service to: California Department of Public Health, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377;
4. Hand-delivered to: Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should contain the regulation package identifier: DPH-14-001E, author's name and mailing address.

AUTHORITY AND REFERENCE

The Department has amended the regulation section identified under the authority provided in sections 124977, 124996, 125000, 125055, 125070 and 131200 of the Health and Safety Code. The regulation implements, interprets, and makes specific sections 124996, 125000, 125001, 125050, 125060, 125065, and 131052 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT
OVERVIEW

This amendment to Title 17, California Code of Regulations (17 CCR), section 6540, increases the California PNS Program's all-inclusive program participation fee for maternal serum alpha fetoprotein (AFP) and additional markers for prenatal screening from \$162 to

\$207, and deletes obsolete references to single marker screening.

Background/Authority

Health and Safety Code (HSC) section 125050 requires the Department to administer a statewide program for prenatal testing for genetic disorders and birth defects, including but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing. HSC sections 125000 and 125050 require the Department to offer information, testing and counseling for genetic disorders and birth defects to all pregnant women in California.

HSC sections 124977(a) and (b), 124996, and 125000(b) require the Department to charge a fee for any tests or activities performed under the program; mandate that the program be fully supported from fees collected; and state that the amount of the fee shall be established by regulation and periodically adjusted by the Director. HSC section 124996 also specifies that the Genetic Disease Testing Fund (GDTF) is a special fund in the State Treasury and is continuously appropriated to the Department to carry out the purposes of the Hereditary Disorders Act. Fees for participation in the California Prenatal Screening (PNS) Program are paid to the Department’s Genetic Disease Screening Program (GDSP) by a participating woman’s health insurance policy or health care service plan or by Medi-Cal for beneficiaries.

If the participation fee is not paid by a third party payer, the fee is paid by the participating woman. The majority of funds are deposited in the GDTF with \$10 deposited in the Birth Defects Monitoring Program Fund, as mandated by HSC section 124977(b). GDSP is not funded by the State’s General Fund. The regulation that implements, interprets, and makes specific these provisions for the California PNS Program is 17 CCR, section 6540.

The Legislature has found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures (HSC section 124977(c)(1)).

HSC section 124977 provides authority for the Department to adopt emergency regulations. HSC section 124977(d)(1) specifies that the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare, and that the regulations shall not be subject to the review and approval of the Office of Administrative Law (OAL); shall be submitted directly to the Secretary of State for filing; and shall become effective immediately upon filing by the Secretary of State. Section 124977(d)(1) also requires the Department to conduct a public hearing within 120 days

of filing with the Secretary of State, and to submit to the OAL with the adopted regulation, a final statement of reasons and updated informative digest. HSC section 124977(d)(2) specifies that this emergency regulation shall not be repealed by the OAL and shall remain in effect until revised or repealed by the Department.

Policy Statement Overview

Problem Statement:

The Department’s legislatively-mandated statewide program for prenatal testing for genetic disorders and birth defects, known as the California PNS Program, must be fully supported by fees charged for maternal serum screening and authorized follow-up services, as required by HSC sections 124977(a) and (b), 124996, and 125000(b). The Legislature has also found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures.

Approximately 370,000 pregnant women participate in the voluntary California PNS Program each year, but caseloads have been overstated in budget estimates for recent fiscal years and revenue projections have not been met. This, along with rising costs, has led to cumulative and annual deficits since Fiscal Year (FY) 2010–11, which must be addressed.

Objectives:

This emergency amendment to 17 CCR, section 6540 is necessary to increase the voluntary participation fee for the California PNS Program to ensure the program remains solvent and continues to meet the legislative mandate of offering information, testing and counseling for genetic disorders and birth defects to all pregnant women in California.

The fee increase will allow the California PNS Program to recoup the cumulative deficit and fund the continuous maintenance costs of the operational and administrative functions of the program.

Benefits:

HSC section 124975(c) declares the findings of the legislature that detection through screening of hereditary disorders can lead to the alleviation of the disability of some hereditary disorders and contribute to the further understanding and accumulation of medical knowledge about hereditary disorders that may lead to their eventual alleviation or cure. The anticipated benefit from this regulatory action is ensuring the California PNS Program remains solvent and able to meet this legislative mandate.

Without a fee increase, the California PNS Program would need to suspend or reduce prenatal screening and diagnostic testing for pregnant women and their unborn children due to lack of funds. Many pregnant women

would not receive genetic screening, counseling or prenatal diagnostic services through the State’s program, as required by statute. Healthcare providers and families would not have the necessary information to plan for appropriate care and/or services before the birth of the child to have resources available to assist the child, such as ready cardiopulmonary resuscitation; neonatal infant transport to a tertiary care facility; early planning for and/or immediate access to pediatric surgery for abnormal cardiac, neurological, and/or gastric conditions; and required social services.

Such planning serves to optimize the health of newborns with birth defects and can reduce stress for the family unit. Advance planning for a high-risk delivery in an appropriate health care setting may reduce and/or ameliorate the severity of the condition and improve quality of life. Without proper planning, some conditions will be compounded. Maintaining the operations and administrative functions of the California PNS Program allows for continued effective planning based on the screening and diagnostic information obtained, resulting in reduced healthcare costs in the short term and over a lifetime for a patient, families, communities, and healthcare businesses.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department evaluated whether the regulation is inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department’s existing state regulations and those regulations specific to prenatal screening regulations. An internet search or other state agency regulations was also performed and it was determined that no other state agency regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this regulation is not inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable..

FORMS INCORPORATED BY REFERENCE

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

REPORTING REQUIREMENT

None.

LOCAL MANDATE

The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

FISCAL IMPACT ESTIMATE

A. COST OR SAVINGS TO ANY STATE AGENCY:

It is estimated that the accumulated deficit in the Genetic Disease Testing Fund will be approximately \$18 million by the end of FY 2013–14. The fee increase will allow the California PNS program to recoup the \$18 million required to offset the cumulative deficit in the Genetic Disease Testing Fund, and ensure program revenue meets program expenses in future years.

Approximately 45 percent of pregnant women participating in the California PNS Program are Medi-Cal beneficiaries. The Department estimates the \$45 fee increase will result in an annual cost to Medi-Cal of \$3.8 million from the General Fund. The \$45.00 fee increase has been fully incorporated into Medi-Cal base data as an ongoing cost; therefore, the fiscal impact will be absorbed by the State’s General Fund.

B. COST TO ANY LOCAL AGENCY OR SCHOOL DISTRICT: None.

C. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED ON LOCAL AGENCIES: None.

D. COST OR SAVINGS ON FEDERAL FUNDING OF STATE PROGRAMS: The Department estimates the \$45 fee increase will result in an annual cost to Federal Financial Participation in Medi-Cal of \$3.8 million. The additional federal funding required under this emergency regulation has been recognized by Medicaid as an ongoing cost.

COST IMPACT ON REPRESENTATIVE PERSON OR BUSINESS

The Department has determined that a cost increase of \$45 per pregnancy in the California PNS Program fee

will be incurred by those businesses providing health coverage to pregnant women. The full or partial cost is charged to the pregnant woman if the fee is not fully covered by health care insurance.

HOUSING COSTS

The Department has determined that the regulation will not have an impact on housing costs.

EFFECT ON SMALL BUSINESS

The Department has determined that the rulemaking has no impact on small businesses, as defined under Government Code Chapter 3.5, Article 2, section 11342.610. The Department is not aware of any small businesses that provide health insurance to pregnant women.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY TO COMPETE

The Department has made an initial determination that the regulatory action will not have a significant statewide adverse economic impact directly effecting California business enterprises or individuals, including the ability of California businesses to compete with businesses in other states. The regulation does not affect contracts or reimbursement rates for contract vendors. The impact to insurers in processing the change in the participation fee will be minimal. The cost impact to insurers of \$45 for each covered pregnancy is unlikely to have a significant impact on any affected business. It is unlikely that the fee increase will be sufficient to require any significant increase in premiums charged to insurance/health plan members.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has determined that the rulemaking will not significantly impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. This regulation does not affect worker safety or California's environment. This regulation will benefit the health and welfare of California residents.

ALTERNATIVES CONSIDERED

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department has made an initial determination that there are no acceptable alternatives to the regulation to fund the operations of the California PNS Program and protect the public interest in maintaining a statewide screening program.

CONTACT PERSON

Inquiries regarding the substance of the regulation described in this notice may be directed to Sara Goldman, M.P.H., Chief, Genetic Disease Screening Program, at (510) 412-1463.

All other inquiries concerning the action described in this notice may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

In any inquiries or written comments, please identify the action by using the Department regulation package identified, DPH-14-003E.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the regulation, all the information upon which the amendments to the regulation are based upon and the text of the regulations. The Office of Regulations is located at 1415 L Street, Suite 500, Sacramento, CA 95814, and is the location of the public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents, please call (916) 440-7673 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation that is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order Decisions Pending & Opportunity for Public Participation, Proposed Regulations.

TITLE 22. OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT

California Coronary Artery Bypass Graft Outcomes Reporting Program

TITLE 22, DIVISION 7, CHAPTER 10, ARTICLE 7: CABG DATA REPORTING REQUIREMENTS

NOTICE IS HEREBY GIVEN that the Office of Statewide Health Planning and Development (OSHPD) proposes to amend Section 97174 of the California Code of Regulations (CCR), Title 22, Division 7, Chapter 10, Article 7.

Amending Section 97174 will add, delete and/or revise certain hospital reported data elements in the California Coronary Artery Bypass Graft Outcomes Reporting Program (CCORP) to conform to the national Society of Thoracic Surgeons (STS) database and to improve risk analysis and outcomes reporting.

I. PUBLIC HEARING

No public hearing is scheduled. Any interested person, or his or her duly authorized representative, may submit a written request for a public hearing, pursuant to Section 11346.8(a) of the Government Code. The written request for a hearing must be received by OSHPD's contact person, designated below, no later than 15 days prior to the close of the written comment period.

II. WRITTEN COMMENT PERIOD AND CONTACT PERSON

Any interested person may submit written comments relevant to the proposed regulatory action. All such comments must be received by OSHPD no later than 3:00 p.m. on 10/20/2014.

Inquiries and comments concerning the proposed regulations should be addressed to the primary contact person named below. Comments delivered by e-mail are preferred. Comments may also be faxed, hand delivered, or mailed to:

Lisa A. Christensen (Cook)
Contract Manager, Clinical Data Programs
Healthcare Outcomes Center
Office of Statewide Health Planning and Development
400 R Street, Room 250
Sacramento, CA 95811-6213
Tel: (916) 326-3867 — Fax: (916) 322-9718
E-mail: lisa.cook@oshpd.ca.gov

Inquiries and comments may also be addressed to the backup contact person:

Holly Hoegh, PhD.
Manager, Clinical Data Programs
Healthcare Outcomes Center
Office of Statewide Health Planning and Development
400 R Street, Room 250
Sacramento, CA 95811-6213
Tel: (916) 326-3868, Fax: (916) 322-9718
E-mail: holly.hoegh@oshpd.ca.gov

Each comment should include the author's name, U.S. Postal Service address, and email address, if applicable, so that the addressee may be included in future communications if the text of the currently proposed regulations changes.

Following the public comment period, OSHPD may adopt the proposal substantially as described below or, after considering all comments, recommendations, and objections regarding the proposed updates, may modify the proposal and offer a second public comment period. With exception of technical grammatical changes, the full text of any modified proposal will be available on the OSHPD website for at least 15 days prior to its adoption. If there is a modified proposal it may also be available by contacting the person(s) designated in this notice.

III. AUTHORITY AND REFERENCE

Authority: California Health and Safety Code, Section 128810. Reference: California Health and Safety Code, Section 128745.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Health and Safety Code Section 128745 requires that on an annual basis OSHPD prepare and publish risk-adjusted outcome reports for coronary artery bypass graft (CABG) surgeries performed in California hospitals. In order to produce these reports, OSHPD is mandated to collect certain data from these hospitals.

Section 97172 of Title 22, California Code of Regulations mandates that every six (6) months, hospitals performing CABG surgeries file a report with OSHPD that contains certain patient level information. Known as the California CABG Outcomes Reporting Program (CCORP), this program collects data from each hospital for each CABG patient.

Currently, CABG surgeries are performed in 125 hospitals. The reported data includes demographic and clinical data elements from the patient medical record. OSHPD analyzes the data, along with data collected from other sources, and prepares the risk-adjusted outcome reports that compare outcomes by hospital and, in every other year, by hospital and cardiac surgeon.

Health and Safety Code Sections 128745 and 128748 provide for the appointment of a nine (9) member Clinical Advisory Panel (CAP) to advise OSHPD on aspects of the CABG program. OSHPD must seek the recommendations of the CAP before making changes to the data elements collected for CCORP.

The CAP may recommend to OSHPD the addition of any element that is included in the Society of Thoracic Surgeons (STS) database. The STS is the industry leader in defining and establishing data elements related to adult cardiac surgery. STS has its own data programs and maintains a data base for CABG surgery. Eighty (80%) percent of California hospitals use the STS database.

In addition, the CAP may recommend that OSHPD add, delete or revise data elements that are not in the STS database, but OSHPD may not add more than a net of six (6) elements that are not in the STS database over any five-year period. This proposal does not add any non-STS elements. On March 4, 2014, the CAP met and reviewed the revisions reflected in the proposed regulatory changes. It was their unanimous recommendation to accept these changes.

CCORP data elements are defined in section 97174 of Title 22, California Code of Regulations. OSHPD proposes to amend section 97174, to add, delete, and re-

vis data elements to be reported. The changes will update the CCORP data and make it consistent with changes in the STS database.

The data elements and definitions in the current regulations will continue to apply for any patients discharged between July 1, 2011 and June 30, 2014. The proposed changes will apply for discharges on and after July 1, 2014.

Reporting requirements for discharges from July 1, 2011 through June 30, 2014 will not be repealed. Reporting requirements for discharges prior to July 1, 2011 will be repealed since they will no longer be relevant.

There are no existing comparable Federal Regulations or Statutes.

V. EFFECT OF THE PROPOSED AMENDMENT

The objective of the proposed amendment to the regulation is to: 1) align 60 CCORP data element definitions with STS definitions version 2.81; 2) add 5 additional STS data elements to the CCORP database; and 3) remove 2 data elements. This proposal does not add any non-STS data elements.

The effect of this update will decrease the burden to hospitals that report to both STS and CCORP by decreasing the need for manual data abstraction and data entry. In addition, updating the data elements collected on CABG surgery will improve and expand risk-adjusted outcomes analysis and reporting for mortality and complications of isolated CABG surgery.

Furthermore, it will allow California to compare its data to data collected by other programs that use these definitions. These changes would also enrich the CCORP reports by providing a better reflection of the quality of care given by hospitals and surgeons in California, which may benefit the health and welfare of California residents.

VI. DETERMINATIONS OF INCONSISTENCY/INCOMPATIBILITY WITH EXISTING STATE REGULATIONS

As required by Government Code Section 11346.5(a)(3)(D), OSHPD has evaluated the language contained in the proposed amendment to Section 97174 of Title 22, Division 7, Chapter 10, Article 7 of the California Code of Regulations.

This amendment does not create conflicting rights, responsibilities, or obligations with other regulations. Based on review and analysis of existing state regulations, OSHPD is unaware of any inconsistencies or conflicts created by the proposed changes.

VII. DISCLOSURES REGARDING THE PROPOSED ACTION

OSHPD has made the following initial determinations:

1. **Mandate on local agencies and school districts:** None.
 2. **Estimated costs or savings to any state agency:** The estimated cost to OSHPD for programming the online reporting system for the revised data elements is absorbable.
 3. **Costs to any local agency or school district that is required to be reimbursed by the state in accordance with Government Code Sections 17500 through 17630:** None. Local agencies and schools do not report data to CCORP.
 4. **Other non-discretionary cost or savings imposed on local agencies:** None.
 5. **Cost or savings in federal funding to the state:** None.
 6. **Significant impact on housing costs:** None.
 7. **Cost impact on representative persons or businesses:** OSHPD estimates that the increased cost to hospitals who report their CABG surgery data to CCORP with the proposed regulatory change is \$924.
 8. **Potential significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states:** OSHPD has determined that the regulations would not have a significant statewide adverse impact on businesses.
 9. **Business reporting requirement:** Hospitals that perform CABG surgeries are required by statute to report CABG surgery data elements to OSHPD. These regulatory changes update the data reported.
- In accordance with Government Code Sections 11346.5(a)(11) and 11346.3(d), OSHPD finds that it is necessary for the health, safety, or welfare of the people of this state that the proposed regulations, which require a report, to apply to businesses.
10. **Small business determination:** The proposed regulatory action does not affect small business. The health care facilities affected by the action either have more than 150 beds or more than \$1,500,000 in annual gross receipts. In accordance with Government Code Section 11342.610, these health care facilities are not defined as small businesses.

VIII. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS (EIA)

Alignment of OSHPD data elements with the STS data base will have minimal economic impact. Hospitals incur nominal annual costs due to changes in data collection relative to data entry and data corrections, a necessary component of reporting to CCORP.

Therefore, OSHPD has concluded that the regulations would not significantly affect the following:

- (1) creation of jobs within the state;
- (2) elimination of jobs within the State of California;
- (3) creation of new businesses within California;
- (4) elimination of existing businesses within California;
- (5) expansion of businesses currently doing business in the state; and
- (6) the benefit to the public is that more accurate and useful data will be available. Such data are used for understanding California's healthcare environment, which may benefit the health and welfare of California residents.

IX. REASONABLE ALTERNATIVES STATEMENT

In accordance with Government Code Section 11346.5(a)(13), OSHPD must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency:

- (1) would be more effective in carrying out the purpose for which the action is proposed;
- (2) would be as effective and less burdensome to affected private persons than the proposed action, or;
- (3) would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

X. AVAILABILITY OF EXPRESS TERMS, INITIAL STATEMENT OF REASONS, AND INFORMATION UPON WHICH PROPOSED RULEMAKING IS BASED

a. Availability of Express Terms

The text of the proposed regulations will be available on OSHPD's website at: <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>. A hardcopy will be available from OSHPD upon request. The text of the proposed regulations will also be available for review from the designated contact person.

b. Availability of Initial Statement of Reasons

The text of the Initial Statement of Reasons will be available on the OSHPD website at: <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>. A hardcopy is available upon request from the designated contact person.

c. Availability of Information upon which Proposed Rulemaking is based

In developing these regulations, OSHPD conducted a survey of affected hospitals. These hospitals were asked to estimate the fiscal impact to their hospitals. Copies of the survey and survey results will be made available upon request.

XI. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

The text of any modified regulation (unless the modification is non-substantial or solely grammatical in nature) will be made available on OSHPD's website for at least 15 days prior to the date OSHPD adopts the regulations as revised at:

<http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>

These changes will be underlined where text is added and struck through where text is deleted. OSHPD may adopt, amend or repeal the foregoing proposal substantially as set forth without further notice.

XII. AVAILABILITY OF FINAL STATEMENT OF REASONS AND RULEMAKING FILE

The Final Statement of Reasons including a summary of Comments and the Responses will be available, after its completion, from the OSHPD website at:

<http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.

The complete Rulemaking File will be available for review from contact person listed in this Notice.

XIII. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, Initial Statement of Reasons, and the text of the regulations in underline and strikeout can be accessed from our website at: <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.

GENERAL PUBLIC INTEREST

CALIFORNIA ENERGY COMMISSION

The Publication of Notice of Adoption of 20 Cal. Code Regs. Section 1609, was submitted by the California Energy Commission, to the Office of Administrative Law on August 18, 2014, for publication on August 29, 2014 (Notice File Number Z-2014-0818-01).

The following amendments are made to the Notice.

Under the heading "NOTICE THAT A PUBLIC HEARING IS SCHEDULED," the date and time for the public hearing is amended to read:

MONDAY OCTOBER 20, 2014
Beginning 2 p.m.
CALIFORNIA ENERGY
COMMISSION
Hearing Room A
1516 9th Street
Sacramento, CA 95814

(Replace "10 a.m." with "2:00 p.m.")

Under the heading "ORAL AND WRITTEN STATEMENTS," the following sentence is added after the third sentence of the first paragraph:

To facilitate the discussion of comments at the hearing, interested persons are encouraged to submit comments by October 13, 2014.

Any inquiries regarding this correction should be made to Galen Lemei, Senior Attorney, California Energy Commission, 1516 9th Street, Sacramento, California 95814; telephone (916) 654-4783, or by email at Galen.Lemei@energy.ca.gov.

SUMMARY OF REGULATORY ACTIONS

REGULATIONS FILED WITH SECRETARY OF STATE

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA 95814, (916) 653-7715. Please have the agency name and the date filed (see below) when making a request.

File# 2014-0711-01
AIR RESOURCES BOARD
Section 100 — Repeal of Adjudicatory Hearings

As a change without regulatory effect, the Air Resources Board is repealing Article 1, sections

60040–60053, of Subchapter 1.25 that governed the procedures for adjudicatory hearings for purposes of reviewing executive officer decisions covered by section 60040(a) issued prior to 10/1/1999. Article 2 of Subchapter 1.25 governs adjudicatory hearings for purposes of reviewing executive officer decisions issued on or after 10/1/1999.

Title 17
 California Code of Regulations
 REPEAL: 60040, 60041, 60042, 60043, 60044, 60045, 60046, 60047, 60048, 60049, 60050, 60051, 60052, 60053
 Filed 08/21/2014
 Agency Contact: Amy Whiting (916) 322–6533

File# 2014–0717–02
 BOARD OF EDUCATION
 LCFF Kindergarten–3 Grade Span Adjustment

This rulemaking action is the Certificate of Compliance action which makes permanent emergency regulations implementing California Education Code section 42238.02 and the Local Control Funding Formula for Kindergarten through third grade Grade Span Adjustment purposes. The regulations specify how average class enrollment of not more than 24 students is calculated, including in situations such as combined classes, new school sites, and reorganized districts, so as to establish an auditable methodology for calculating these averages and measuring progress toward class size reduction objectives and the granting of Grade Span Adjustments to local education agencies.

Title 5
 California Code of Regulations
 ADOPT: 15498, 15498.1, 15498.2, 15498.3
 Filed 08/25/2014
 Effective 08/25/2014
 Agency Contact: Hillary Wirick (916) 319–0644

File# 2014–0717–03
 BOARD OF EDUCATION
 Charter Revocation

The State Board of Education repeals section 11968.5 of title 5 of the California Code of Regulations, which is no longer consistent with recently–amended Education Code sections.

Title 5
 California Code of Regulations
 REPEAL: 11968.5
 Filed 08/27/2014
 Effective 10/01/2014
 Agency Contact: Hillary Wirick (916) 319–0644

File# 2014–0716–04
 BOARD OF EDUCATION
 Measurement of Academic Performance & Progress

The State Board of Education submitted this timely certificate of compliance to make permanent the emergency regulations adopted in OAL file no. 2014–0124–04E and re–adopted in OAL file no. 2014–0716–03EE. The emergency rulemaking amended and repealed sections of Title 5 of the California Code of Regulations commencing with section 850 and ending with section 868 to implement Education Code section 60640, which deleted provisions that established the Standardized Testing and Reporting Program and established California Assessment of Student Performance and Progress. Changes were made to the emergency regulations during the permanent rulemaking process.

Title 5
 California Code of Regulations
 ADOPT: 853.7 AMEND: 850, 851, 852, 853, 853.5, 855, 857, 858, 859, 861, 862, 862.5, 863, 864 REPEAL: 854, 864.5, 865, 866, 867, 867.5, 868
 Filed 08/27/2014
 Effective 08/27/2014
 Agency Contact: Hillary Wirick (916) 319–0644

File# 2014–0710–01
 BOARD OF EQUALIZATION
 Business Inventory Exemption

The Board of Equalization amended section 133 of title 18 of the California Code of Regulations to include certain space flight property, not operationally reusable, the control over which is relinquished by the owner on launch, as business inventory eligible for exemption from taxation under section 219 of the Revenue and Taxation Code.

Title 18
 California Code of Regulations
 AMEND: 133
 Filed 08/21/2014
 Effective 10/01/2014
 Agency Contact:
 Richard E. Bennion (916) 445–2130

File# 2014–0711–02
 BOARD OF VOCATIONAL NURSING AND PSYCHIATRIC TECHNICIANS
 Permissive Site Visits

This regulatory action amends sections 2526 and 2581 of the California Code of Regulations to allow the Board to inspect or review all vocational nursing and psychiatric technician programs within the state.

Title 16
 California Code of Regulations
 AMEND: 2526, 2581
 Filed 08/21/2014
 Effective 10/01/2014
 Agency Contact: Pam Hinckley (916) 263-7840

File# 2014-0716-02
 DEPARTMENT OF CORRECTIONS AND
 REHABILITATION
 Parole Revocation Realignment

In this certificate of compliance, the Department is making permanent the adoption and amendment of various sections in title 15 of the California Code of Regulations to comply with Assembly Bill 109, which re-directs low-level felony offenders and reforms parole. The regulations add a number of definitions, update existing forms, introduce new forms, and elaborate on the new procedures imposed by the new criminal justice laws related to the Criminal Justice Realignment.

Title 15
 California Code of Regulations
 ADOPT: 3750, 3751, 3752, 3753, 3754, 3756, 3760, 3761, 3761.1, 3762, 3763, 3764, 3765, 3766
 AMEND: 3000, 3075.2, 3768.2, 3768.3
 Filed 08/27/2014
 Effective 08/27/2014
 Agency Contact: Rosie Ruiz (916) 445-2244

File# 2014-0822-01
 DEPARTMENT OF FOOD AND AGRICULTURE
 Asian Citrus Psyllid Interior Quarantine

This emergency regulatory action expands the quarantine area for the Asian Citrus Psyllid (ACP) "Diaphorina citri" by approximately 97 square miles in the San Luis Obispo area. The action also creates a quarantine area for ACP in the Cayucos area of approximately 61 square miles. The effect of the emergency action provides authority for the state to perform quarantine activities against ACP within these additional areas, along with the existing regulated areas in the entire counties of Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara, and Ventura, and a portion of Fresno, Kern and Tulare counties that are already under quarantine for the ACP, totaling approximately 46,702 square miles.

Title 3
 California Code of Regulations
 AMEND: 3435(b)
 Filed 08/25/2014
 Effective 08/25/2014
 Agency Contact: Lindsay Rains (916) 654-1017

File# 2014-0714-02
 DEPARTMENT OF INSURANCE
 2014 Commercial Rate Application

This File/Print action amends Title 10 of the California Code of Regulations section 2498.5 and the California Automobile Assigned Risk Plan Rules and Rates Manual. Rules 57, 73, 75, 122, 123, and 124 are revised to adjust rates for commercial auto assigned risk insurance policies by an overall 17.6 percent. This action is exempt from OAL review per the APA "rates, prices, or tariffs" exemption contained in Government Code section 11340.9(g).

Title 10
 California Code of Regulations
 AMEND: 2498.5
 Filed 08/21/2014
 Effective 08/21/2014
 Agency Contact: Mike Riordan (415) 538-4226

File# 2014-0715-02
 DEPARTMENT OF PESTICIDE REGULATION
 Groundwater Protection List

This rulemaking action updates the list of pesticide chemicals which have the potential to pollute ground water and which are listed in section 6800(b) of Title 3 of the California Code of Regulations.

Title 3
 California Code of Regulations
 AMEND: 6800
 Filed 08/25/2014
 Effective 10/01/2014
 Agency Contact:
 Linda Irokawa-Otani (916) 445-3991

File# 2014-0716-01
 DIVISION OF WORKERS' COMPENSATION
 Workers' Compensation — Medical Provider Networks

This rulemaking action by the Division of Workers' Compensation makes changes to the Medical Provider Network (MPN) regulations in Title 8, Article 3.5 of the California Code of Regulations intended to implement statutory changes enacted by Statutes 2012, Chapter 363 (SB 863). The regulations expand eligibility to have MPNs to include entities that provide physician network services, amend the MPN application process, facilitate administrative review, and limit MPN approvals to a period of four years. The amendments also provide a complaint process, disciplinary provisions, random review, and procedures for imposition of penalties, probation, suspension, and revocation of an MPN and an appeals process for challenging any such disciplinary action.

Title 8
 California Code of Regulations
 ADOPT: 9767.5.1, 9767.16.5, 9767.17, 9767.17.5,
 9767.18, 9767.19 AMEND: 9767.1, 9767.2, 9767.3,
 9767.4, 9767.5, 9767.6, 9767.7, 9767.8, 9767.9,
 9767.10, 9767.11, 9767.12, 9767.13, 9767.14,
 9767.15, 9767.16
 Filed 08/27/2014
 Effective 08/27/2014
 Agency Contact: John G. Cortes (510) 286-7100

File# 2014-0213-02
FISH AND GAME COMMISSION
 Low Flow Closure to Fishing Due to Drought
 Conditions

This emergency regulatory action temporarily closes specified streams to fishing to protect vulnerable migrating anadromous fish, primarily wild steelhead trout.

Title 14
 California Code of Regulations
 AMEND: 7.00, 7.50, 8.00
 Filed 08/21/2014
 Effective 08/21/2014
 Agency Contact: Jon Snellstrom (916) 654-4899

File# 2014-0815-02
FISH AND GAME COMMISSION
 Merced River Closure Due to Drought Conditions

This emergency filing is in response to the state's drought conditions and its effect on the Merced River's rainbow trout population. Specifically, the filing amends 14 CCR § 7.50 (b)(118) to close the remainder of the open fishing season for a defined segment of the Merced River. Both resident and steelhead rainbow trout exist in the Merced River downstream of the Crocker-Huffman Dam. The amendment to 14 CCR § 7.50 (b)(118)(A), when read in conjunction with 14 CCR § 7.50(a)(2), closes the portion of the Merced River from Crocker-Huffman Dam downstream to the Snelling Road bridge to all fishing all year. (See CCR, tit. 14, § 7.50, subd. (a)(2) ["Every body of water listed below is closed to all fishing except during the open season as shown."].) The amendment is necessary to preserve the rainbow trout population in the Merced River.

Title 14
 California Code of Regulations
 AMEND: 7.50
 Filed 08/25/2014
 Effective 08/25/2014
 Agency Contact: Jon Snellstrom (916) 654-4899

File# 2014-0722-02
OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD
 Lockout Tagout (LOTO)—Group Lockout

The Occupational Safety and Health Standards Board amended section 3314 of title 8 of the California Code of Regulations to add a group lockout/tagout requirement consistent with section 2910.147(f)(3) and (f)(4) of title 29 of the Code of Federal Regulations.

Title 8
 California Code of Regulations
 AMEND: 3314
 Filed 08/25/2014
 Effective 10/01/2014
 Agency Contact: Marley Hart (916) 274-5721

File# 2014-0714-03
STATE LANDS COMMISSION
 Amendment to Architectural and Engineering (A&E)
 Contracting Regulations

This action adopts and amends regulations regarding contracts for architecture and engineering (A&E) services pursuant to Government Code section 4525, et seq. The action clarifies existing statutes, establishes criteria for reviewing A&E firms, adopts rules regarding annual statements of qualifications, establishes procedures where fewer than three firms bid, and adopts rules regarding retainer contracts.

Title 2
 California Code of Regulations
 ADOPT: 2980.5, 2980.11 AMEND: 2980.1, 2980.3,
 2980.5(a) (Renumbered to 2980.6(b)), 2980.5(b)
 (Renumbered to 2980.6(c)), 2980.5(c) (Renumbered
 to 2980.6(d)), 2980.6 (Renumbered to
 2980.7), 2980.7(a) (Renumbered to 2980.8(a) and
 2980.8(b)), 2980.7(b) (Renumbered to 2980.9(a)),
 2980.7(c) (Renumbered to 2980.9(b)), 2980.8 (Re-
 numbered to 2980.10), 2980.9 (Renumbered to
 2980.12)
 Filed 08/25/2014
 Effective 10/01/2014
 Agency Contact: Christopher Huitt (916) 574-2080

File# 2014-0714-01
SUPERINTENDENT OF PUBLIC INSTRUCTION
 Migrant Education Statewide Parent Advisory Council

This rulemaking action by the State Superintendent of Public Instruction (SSPI) adopts fifteen sections under title 5 of the California Code of Regulations that pertain to the Migrant Education Program (MEP). Education Code section 54444.2(a)(2) directs the SSPI to establish a Statewide Parent Advisory Council (SPAC) to participate in the planning, operation, and evaluation of the MEP. This rulemaking action is in-

tended to promote the orderly, efficient, and fiscally prudent operation of the SPAC, encourage compliance with state and federal law, promote openness and transparency, and maximize parental participation.

Title 5

California Code of Regulations

ADOPT: 12030, 12031, 12032, 12033, 12034, 12035, 12036, 12037, 12038, 12039, 12040, 12041, 12042, 12043, 12044

Filed 08/25/2014

Effective 10/01/2014

Agency Contact: Hillary Wirick (916) 319-0644

**CCR CHANGES FILED
WITH THE SECRETARY OF STATE
WITHIN March 26, 2014 TO
August 27, 2014**

All regulatory actions filed by OAL during this period are listed below by California Code of Regulations titles, then by date filed with the Secretary of State, with the Manual of Policies and Procedures changes adopted by the Department of Social Services listed last. For further information on a particular file, contact the person listed in the Summary of Regulatory Actions section of the Notice Register published on the first Friday more than nine days after the date filed.

Title 2

- 08/25/14 ADOPT: 2980.5, 2980.11 AMEND: 2980.1, 2980.3, 2980.5(a) (Renumbered to 2980.6(b)), 2980.5(b) (Renumbered to 2980.6(c)), 2980.5(c) (Renumbered to 2980.6(d)), 2980.6 (Renumbered to 2980.7), 2980.7(a) (Renumbered to 2980.8(a) and 2980.8(b)), 2980.7(b) (Renumbered to 2980.9(a)), 2980.7(c) (Renumbered to 2980.9(b)), 2980.8 (Renumbered to 2980.10), 2980.9 (Renumbered to 2980.12)
- 08/19/14 AMEND: 1859.90.2, 1859.90.3, 1859.193, 1859.197
- 08/12/14 ADOPT: 18700.3 AMEND: 18438.5 REPEAL: 18703.1
- 08/12/14 ADOPT: 649.24 AMEND: 649, 649.4, 649.8, 649.26, 649.29, 649.32, 649.40, 649.43
- 08/07/14 ADOPT: 18422, 18422.5 AMEND: 18215, 18427.1 REPEAL: 18412
- 07/30/14 AMEND: 679
- 07/14/14 AMEND: 549
- 05/30/14 REPEAL: 649.56
- 05/29/14 AMEND: 22600, 22600.1, 22600.2, 22600.5, 22600.6, 22600.7, 22600.8,

- 22600.9, 22601, 22601.3, 22601.4, 22601.7 REPEAL: 22601.1
- 05/19/14 ADOPT: 1181.1, 1181.2, 1181.3, 1181.4, 1181.5, 1181.6, 1181.7, 1181.8, 1181.9, 1181.10, 1181.11, 1181.12, 1181.13, 1182.1, 1182.2, 1182.3, 1182.4, 1182.5, 1182.6, 1182.7, 1182.8, 1182.9, 1182.10, 1182.11, 1182.12, 1182.13, 1182.14, 1182.15, 1182.16, 1183.1, 1183.2, 1183.3, 1183.4, 1183.5, 1183.6, 1183.7, 1183.8, 1183.9, 1183.10, 1183.11, 1183.12, 1183.13, 1183.14, 1183.15, 1183.16, 1183.17, 1183.18, 1184.1, 1185.1, 1185.2, 1185.3, 1185.4, 1185.5, 1185.6, 1185.7, 1185.8, 1185.9, 1186.1, 1186.2, 1186.3, 1186.4, 1186.5, 1186.6, 1186.7, 1187.1, 1187.2, 1187.3, 1187.4, 1187.5, 1187.6, 1187.7, 1187.8, 1187.9, 1187.10, 1187.11, 1187.12, 1187.13, 1187.14, 1187.15, 1188.1, 1188.2, 1190.1, 1190.2, 1190.3, 1190.4, 1190.5 REPEAL: 1181, 1181.1, 1181.2, 1181.4, 1182, 1182.1, 1182.2, 1182.3, 1182.4, 1182.5, 1183, 1183.01, 1183.02, 1183.03, 1183.04, 1183.05, 1183.06, 1183.07, 1183.08, 1183.081, 1183.09, 1183.1, 1183.11, 1183.12, 1183.13, 1183.131, 1183.14, 1183.2, 1183.21, 1183.25, 1183.30, 1183.31, 1183.32, 1184.5, 1184.6, 1184.7, 1184.8, 1184.9, 1184.10, 1184.11, 1185, 1185.1, 1185.2, 1185.21, 1185.3, 1185.4, 1185.5, 1185.6, 1185.7, 1186, 1186.5, 1186.51, 1186.52, 1186.53, 1186.54, 1186.55, 1186.6, 1186.61, 1186.62, 1186.63, 1186.64, 1186.65, 1186.7, 1186.71, 1186.72, 1186.73, 1187, 1187.2, 1187.3, 1187.4, 1187.5, 1187.6, 1187.7, 1187.8, 1187.9, 1188, 1188.1, 1188.2, 1188.3, 1188.31, 1188.4, 1189, 1189.1, 1189.2, 1189.3, 1189.6, 1189.61, 1190, 1190.01, 1190.02, 1190.03, 1190.04, 1190.05
- 05/01/14 ADOPT: 18706.1 AMEND: 18706
- 05/01/14 AMEND: 18950.1
- 05/01/14 AMEND: 18705.2 REPEAL: 18704.2
- 04/30/14 AMEND: 18704
- 04/30/14 AMEND: 18707.9
- 04/16/14 ADOPT: 599.760.1 AMEND: 599.757, 599.759, 599.761, 599.768, 599.769 REPEAL: 599.755, 599.760, 599.764, 599.765, 599.766, 599.767
- Title 3**
- 08/25/14 AMEND: 3435(b)
- 08/25/14 AMEND: 6800

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08/18/14	ADOPT: 3162	03/28/14	AMEND:10302,10305,10315,10317,10320,10322,10325,10326,10327, 10328, 10337
08/06/14	AMEND: 6000, 6196, 6400, 6624 REPEAL: 6446, 6446.1		
08/05/14	REPEAL: 3277		
07/22/14	AMEND: 3591.13(a)	Title 5	
07/10/14	AMEND: 3424	08/27/14	REPEAL: 11968.5
06/27/14	AMEND: 1430.142	08/27/14	ADOPT: 853.7 AMEND: 850, 851, 852, 853, 853.5, 855, 857, 858, 859, 861, 862, 862.5, 863, 864 REPEAL: 854, 864.5, 865, 866, 867, 867.5, 868
06/24/14	AMEND: 3435(b)	08/25/14	ADOPT: 15498, 15498.1, 15498.2, 15498.3
06/17/14	AMEND: 3435(b)	08/25/14	ADOPT: 12030, 12031, 12032, 12033, 12034, 12035, 12036, 12037, 12038, 12039, 12040, 12041, 12042, 12043, 12044
06/02/14	AMEND: 3435(b)	07/28/14	ADOPT: 15494, 15495, 15496, 15497
05/14/14	ADOPT: 1280, 1280.1, 1280.8, 1280.10 AMEND: 1280.7	07/23/14	AMEND: 850, 851, 852, 853, 853.5, 855, 857, 858, 859, 861, 862, 862.5, 863, 864 REPEAL: 854, 864.5, 865, 866, 867, 867.5, 868
05/12/14	AMEND: 3591.20(a)	07/11/14	ADOPT: 80693, 80694
04/24/14	AMEND: 3435(b)	06/26/14	ADOPT: 9517.3
04/04/14	AMEND: 3435(b)	06/13/14	ADOPT: 19810 REPEAL: 19810, 19812, 19813, 19814, 19815, 19816, 19816.1, 19817, 19817.1, 19817.2, 19817.5, 19818, 19819, 19820, 19821, 19821.5, 19822, 19823, 19824, 19824.1, 19825, 19825.1, 19827, 19828, 19828.1, 19828.2, 19828.3, 19828.4, 19829, 19829.5, 19830, 19830.1, 19831, 19832, 19833, 19833.5, 19833.6, 19834, 19835, 19836, 19837, 19837.1, 19837.2, 19837.3, 19838, 19840, 19841, 19843, 19844, 19845, 19845.1, 19845.2, 19846, 19846.1, 19847, 19848, 19849, 19850, 19851, 19851.1, 19852, 19853, 19854, 19854.1, 19855
	Title 4	05/19/14	AMEND: 80035.5
08/13/14	AMEND: 7051, 7052, 7057, 7058, 7059, 7065, 7066, 7068	05/05/14	ADOPT: 14037, 14038, 14039, 14040, 14041, 14042
08/13/14	AMEND: 7030, 7031, 7036, 7037, 7038, 7044, 7045, 7047	05/05/14	ADOPT: 3051.19, 3051.20, 3051.21, 3051.22, 3051.23, 3051.24 AMEND: 3001, 3023, 3025, 3029, 3030, 3031, 3040, 3043, 3051, 3051.1, 3051.2, 3051.3,.4, 3051.5, 3051.6, 3051.7, 3051.75, 3051.8, 3051.9, 3051.10, 3051.11, 3051.12, 3051.13, 3051.14, 3051.15, 3051.16, 3051.17, 3051.18, 3060, 3061, 3064, 3065, 3068, 3083, 3084, 3088 REPEAL: 3054
08/06/14	ADOPT: 10170.1, 10170.2, 10170.3, 10170.4, 10170.5, 10170.6, 10170.7, 10170.8, 10170.9, 10170.10, 10170.11, 10170.12, 10170.13, 10170.14, 10170.15	04/15/14	AMEND: 70020
08/06/14	ADOPT: 10170.16, 10170.17, 10170.18, 10170.19, 10170.20, 10170.21, 10170.22, 10170.23, 10170.24	04/01/14	AMEND: 80303
08/05/14	ADOPT: 7113, 7114, 7115, 7116, 7117, 7118, 7119, 7120, 7121, 7122, 7123, 7124, 7125, 7126, 7127, 7128, 7129		
07/10/14	ADOPT: 5600, 5610, 5620, 5630, 5640 AMEND: 5000, 5144, 5170, 5200, 5205, 5230, 5240, 5255, 5350, 5370		
06/30/14	AMEND: 10030, 10031, 10032, 10033, 10034, 10035, 10036		
06/18/14	AMEND: 12505		
06/18/14	AMEND: 8070, 8072		
06/16/14	AMEND: 4001 ADOPT: 4002.9		
06/13/14	AMEND: 8034		
06/11/14	ADOPT: 12387 AMEND: 12360, 12386		
06/09/14	ADOPT: 4402, 4403, 4496, 4496.1, 4496.2, 4496.3, 4496.4, 4496.5, 4496.6		
05/19/14	AMEND: 7030, 7032, 7033, 7034, 7035, 7036, 7037, 7040, 7042		
05/15/14	ADOPT: 7113, 7114, 7115, 7116, 7117, 7118, 7119, 7120, 7121, 7122, 7123, 7124, 7125, 7126, 7127, 7128, 7129		
05/12/14	AMEND: 1632		
04/07/14	AMEND: 1656, 1658		
04/03/14	AMEND: 10030, 10031, 10032, 10033, 10034, 10035, 10036		
04/02/14	AMEND: 2066		

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04/01/14 ADOPT: 15498, 15498.1, 15498.2, 15498.3

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08/27/14 ADOPT: 9767.5.1, 9767.16.5, 9767.17, 9767.17.5, 9767.18, 9767.19 AMEND: 9767.1, 9767.2, 9767.3, 9767.4, 9767.5, 9767.6, 9767.7, 9767.8, 9767.9, 9767.10, 9767.11, 9767.12, 9767.13, 9767.14, 9767.15, 9767.16

08/25/14 AMEND: 3314

07/31/14 AMEND: 4542

07/31/14 ADOPT: 5120

07/10/14 ADOPT: 32036, 32037, 32610, 32611, 32806, 32808, 32810, 95000, 95010, 95020, 95030, 95040, 95045, 95050, 95070, 95080, 95090, 95100, 95150, 95160, 95170, 95180, 95190, 95200, 95300, 95310, 95320, 95330 AMEND: 31001, 32020, 32030, 32040, 32050, 32055, 32060, 32075, 32080, 32085, 32090, 32091, 32100, 32105, 32120, 32122, 32130, 32132, 32135, 32136, 32140, 32142, 32145, 32147, 32149, 32150, 32155, 32162, 32164, 32165, 32166, 32168, 32169, 32170, 32175, 32176, 32178, 32180, 32185, 32190, 32200, 32205, 32206, 32207, 32209, 32210, 32212, 32215, 32220, 32230, 32295, 32300, 32305, 32310, 32315, 32320, 32325, 32350, 32360, 32370, 32375, 32380, 32400, 32410, 32450, 32455, 32460, 32465, 32470, 32500, 32602, 32605, 32612, 32615, 32620, 32621, 32625, 32630, 32635, 32640, 32644, 32645, 32647, 32648, 32649, 32650, 32661, 32680, 32690, 32700, 32720, 32721, 32722, 32724, 32726, 32728, 32730, 32732, 32734, 32735, 32736, 32738, 32739, 32740, 32742, 32744, 32746, 32748, 32750, 32752, 32754, 32761, 32762, 32763, 32770, 32772, 32774, 32776, 32980, 32990, 32992, 32993, 32994, 32995, 32996, 32997

06/24/14 AMEND: 5155

06/03/14 AMEND: 9789.30, 9789.31, 9789.32, 9789.33, 9789.37, 9789.39

06/02/14 AMEND: 5605

05/30/14 ADOPT: 13660, 13660.1, 13661, 13662, 13663, 13663.5, 13664, 13665, 13665.5, 13666, 13666.1, 13666.2, 13666.5, 13667, 13667.1, 13667.40 REPEAL: 13660, 13661, 13662

05/29/14 AMEND: 1598, 1599

05/14/14 ADOPT: 344.76, 344.77

05/05/14 AMEND: 1529, 1532, 1532.1, 1532.2, 1535, 3204, 5150, 5157, 5161, 5189, 5190, 5191, 5192, 5194, 5197, 5198, 5200, 5201, 5202, 5206, 5207, 5208, 5208.1, 5209, 5210, 5211, 5212, 5213, 5214, 5215, 5217, 5218, 5219, 5220, 8358, 8359

05/05/14 ADOPT: 1929 AMEND: 1504, 1930, 1931, 1932, 1934, 1935, 1936, 5154, 5191, 5194, 5415, 5417, 5449, 5451, 5531, 5532, 5533, 5534, 5535, 5537, 5538, 5541, 5542, 5543, 5545, 5546, 5547, 5549, 5555, 5556, 5558, 5560, 5566, 5568, 5569, 5570, 5573, 5574, 5575, 5576, 5577, 5578, 5579, 5580, 5583, 5585.1, 5589, 5590, 5592, 5593, 5594, 5595, 5596, 5597, 5598, 5599, 5601, 5602, 5606, 5607, 5608, 5616, 5617, 5618, 5619, 5620, 5621, 5622, 5624

04/28/14 AMEND: 2940.2, 2940.7, 8602, 8610, 8611, 8615

04/16/14 AMEND: 10205.14 REPEAL: 9788.01, 9788.1, 9788.11, 9788.2, 9788.3, 9788.31, 9788.32, 9788.4, 9788.45, 9788.5, 9788.6, 9788.7, 9788.8, 9788.9, 9788.91

04/14/14 AMEND: 3650

04/14/14 AMEND: 5001

04/09/14 AMEND: 1619.1(b)

04/03/14 AMEND: 4355

04/01/14 AMEND: 1520, 3384

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08/12/14 AMEND: 531, 532, 532.1, 532.2, 532.3, 532.4, 532.5, 532.6, 533, 534, 535

07/29/14 AMEND: 1840.205, 1850.325

06/23/14 AMEND: 4500

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08/21/14 AMEND: 2498.5

08/18/14 ADOPT: 8000, 8010, 8020, 8030, 8070 (re-numbered to 8040) REPEAL: 8040, 8050, 8060

08/14/14 AMEND: 2548.3, 2548.19, 2548.21, 2548.24, 2548.25

08/13/14 AMEND: 250.9, 250.10, 250.11, 250.15, 250.60, 250.61, 260.100.1, 260.100.3, 260.102.8, 260.102.14, 260.102.16, 260.102.19, 260.103.6, 260.105.33, 260.110, 260.131, 260.140.71.2, 260.141.50, 260.146, 260.151, 260.165, 260.241, 260.302, 260.507, 260.608, 260.608.2, 280.100, 280.150, 280.152, 280.153, 280.200, 280.250, 280.300,

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	280.400, 310.002, 310.100.2, 310.101, 310.106, 310.156.1, 310.156.2, 310.156.3, 310.303, 310.304, 1436, 1454, 1718, 1723, 1726, 1787.1, 1799, 1805.204.1, 1950.122.2, 1950.122.4, 1950.204.3, 1950.206, 1950.314.8, 2030		2699.209, 2699.210, 2699.400
	REPEAL: 2031.1, 2031.2, 2031.3, 2031.4, 2031.5, 2031.6, 2031.7, 2031.8, 2031.9, 2031.10		REPEAL: 2699.202, 2699.208, 2699.211
07/31/14	ADOPT: 6456	06/04/14	AMEND: 2698.401
07/23/14	ADOPT: 10.190500, 10.190501	06/02/14	ADOPT: 6540, 6542, 6544, 6546, 6548, 6550, 6552
07/21/14	ADOPT: 6650, 6652, 6654, 6656, 6657, 6658, 6660, 6662, 6664, 6666, 6668, 6670	05/21/14	ADOPT: 6460
		05/12/14	ADOPT: 6650, 6652, 6654, 6656, 6657, 6658, 6660, 6662, 6664, 6666, 6668, 6670
07/17/14	ADOPT: 1600, 1601, 1602, 1603, 1604, 1605, 1606, 1606.1, 1607, 1608, 1609, 1610, 1611, 1612, 1613, 1614, 1615, 1616, 1617, 1618 AMEND: 1550	05/07/14	AMEND: 2498.4.9
	REPEAL: 1580, 1581, 1582, 1583, 1584, 1585, 1586, 1587, 1588, 1589, 1590, 1591, 1592, 1593, 1594, 1595, 1596	04/29/14	AMEND: 2509.1, 2509.3, 2509.4, 2509.5, 2509.6, 2509.7, 2509.8, 2509.9, 2509.10, 2509.11, 2509.12, 2509.13, 2509.14, 2509.15, 2509.16, 2509.17, 2509.18, 2509.19, 2509.20
07/01/14	ADOPT: 6800, 6802, 6804, 6806	04/28/14	AMEND: 2498.6
06/30/14	AMEND: 2705, 2710, 2713, 2718, 2725.5, 2729, 2729.5, 2731, 2742, 2743, 2746, 2752, 2758.4, 2758.5, 2761, 2763, 2790, 2790.8, 2791, 2792.1, 2792.2, 2792.18, 2792.32, 2793, 2795, 2799.2, 2801.5, 2806, 2807.4, 2809, 2809.1, 2809.3, 2810.5, 2831, 2840, 2842, 2845, 2846, 2846.7, 2846.8, 2847, 2847.3, 2848, 2849.01, 2851, 2860, 2910, 2911, 2912, 2922, 2930, 2940, 2945.2, 2945.4, 2963, 3000, 3002, 3004, 3006, 3007, 3007.2, 3007.6, 3009, 3013, 3100, 3101, 3104, 3106, 3107	04/23/14	AMEND: 3541, 3568
		04/23/14	AMEND: 2498.5
		04/21/14	ADOPT: 2907.1, 2907.2, 2907.3, 2907.4
		04/10/14	ADOPT: 2562.1, 2562.2, 2562.3, 2562.4
		04/01/14	ADOPT: 6700, 6702, 6704, 6706, 6708, 6710, 6712, 6714, 6716, 6718
		04/01/14	ADOPT: 6408, 6410, 6450, 6452, 6454, 6470, 6472, 6474, 6476, 6478, 6480, 6482, 6484, 6486, 6490, 6492, 6494, 6496, 6498, 6500, 6502, 6504, 6506, 6508, 6510, 6600, 6602, 6604, 6606, 6608, 6610, 6612, 6614, 6616, 6618, 6620
		04/01/14	ADOPT: 6800, 6802, 6804, 6806
		04/01/14	ADOPT: 6520, 6522, 6524, 6526, 6528, 6530, 6532, 6534, 6536, 6538
		Title 11	
06/30/14	ADOPT: 6520, 6522, 6524, 6526, 6528, 6530, 6532, 6534, 6536, 6538	08/11/14	AMEND: 999.121, 999.129, 999.133, 999.137, 999.141, 999.143, 999.144, 999.145, 999.146, 999.165, 999.166, 999.168, 999.171, 999.172, 999.173, 999.174, 999.176, 999.178, 999.179, 999.190, 999.191, 999.192, 999.193, 999.195, 999.203, 999.204, 999.206, 999.207, 999.209, 999.210, 999.211, 999.217, 999.219, 999.220, 999.221, 999.223
06/30/14	ADOPT: 6408, 6410, 6450, 6452, 6454, 6470, 6472, 6474, 6476, 6478, 6480, 6482, 6484, 6486, 6490, 6492, 6494, 6496, 6498, 6500, 6502, 6504, 6506, 6508, 6510, 6600, 6602, 6604, 6606, 6608, 6610, 6612, 6614, 6616, 6618, 6620	06/11/14	AMEND: 1005, 1007, 1008
06/26/14	ADOPT: 6700, 6702, 6704, 6706, 6708, 6710, 6712, 6714, 6716, 6718	06/05/14	AMEND: 1005, 1007, 1008, 1052
06/26/14	ADOPT: 2696.20, 2696.22, 2696.24, 2696.26, 2696.28, 2696.30, 2696.32	05/29/14	AMEND: 48.6
06/19/14	AMEND: 2698.200	05/20/14	AMEND: 1082
06/18/14	AMEND: 2698.602		
06/16/14	ADOPT: 6458	Title 13	
06/16/14	AMEND: 2699.200, 2699.207	07/10/14	AMEND: 1962.1, 1962.2
06/10/14	AMEND: 2699.100, 2699.200, 2699.201, 2699.205, 2699.207,	06/26/14	AMEND: 550.10, 551, 551.1, 551.6, 553.40, 583, 598

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06/25/14 AMEND: 25.06, 25.07, 25.08, 25.10,
25.14, 25.15, 25.16, 25.17, 25.18, 25.19,
25.20, 21, 25.22, 28.23
06/19/14 REPEAL: 28.22
06/09/14 AMEND: 1160.1, 1160.2, 1160.4
05/19/14 ADOPT: 227.00, 227.02, 227.04, 227.06,
227.08, 227.10, 227.12, 227.14, 227.16,
227.18, 227.20, 227.22, 227.24, 227.26,
227.28, 227.30, 227.32, 227.34, 227.36,
227.38, 227.42, 227.44, 227.46, 227.48,
227.50, 227.52
05/01/14 AMEND: 125.02

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08/25/14 AMEND: 7.50
08/21/14 AMEND: 7.00, 7.50, 8.00
08/12/14 AMEND: 632
08/11/14 ADOPT: 550, 550.5, 551, 630 AMEND:
552, 703 REPEAL: 550, 551, 553, 630
08/07/14 AMEND: 13055
08/04/14 AMEND: 228
07/31/14 AMEND: 18660.23, 18660.24,
18660.25, 18660.33, 18660.34
07/10/14 AMEND: 791.7
07/08/14 AMEND: 7.50
07/02/14 ADOPT: 5200, 5201, 5202, 5203, 5204,
5205, 5206, 5207, 5208, 5209, 5210,
5211, 5300, 5301, 5302, 5303, 5304,
5305, 5306, 5307
06/27/14 ADOPT: 1761, 1780, 1781, 1782, 1783,
1783.1, 1783.2, 1783.3, 1783.4, 1788
06/25/14 AMEND: 28.20
06/23/14 AMEND: 360, 361, 362, 363, 364
06/19/14 AMEND: 916.2, 936.2, 956.2
06/11/14 ADOPT: 923, 923.1, 923.2, 923.3, 923.4,
923.5, 923.6, 923.7, 923.8, 923.9,
923.9.1, 943, 943.1, 943.2, 943.3, 943.4,
943.5, 943.6, 943.7, 943.8, 943.9,
943.9.1, 963, 963.1, 963.2, 963.3, 963.4,
963.5, 963.6, 963.7, 963.8, 963.9,
963.9.1 AMEND: 895.1, 914.7, 914.8,
915.1, 916.3, 916.4, 916.9, 934.7, 934.8,
935.1, 936.3, 936.4, 936.9, 954.7, 954.8,
955.1, 956.3, 956.4, 956.9, 1034, 1051.1,
1090.5, 1090.7, 1092.09, 1093.2, 1104.1
REPEAL: 918.3, 923, 923.1, 923.2,
923.3, 923.4, 923.5, 923.6, 923.7, 923.8,
923.9.1, 938.3, 943, 943.1, 943.2, 943.3,
943.4, 943.5, 943.6, 943.7, 943.8, 943.9,
943.9.1, 958.3, 963, 963.1, 963.2, 963.3,
963.4, 963.5, 963.6, 963.7, 963.8, 963.9
06/11/14 AMEND: 3550.8
05/22/14 AMEND: 165
05/21/14 AMEND: 360

05/19/14 AMEND: 149, 149.1
04/30/14 AMEND: 27.80
04/11/14 AMEND: 3550.15
04/07/14 AMEND: 790, 820.01
04/01/14 AMEND: 27.80
03/26/14 AMEND: 916.9(g)(2)(A),
936.9(g)(2)(A), 956.9(g)(2)(A)

Title 15

08/27/14 ADOPT: 3750, 3751, 3752, 3753, 3754,
3756, 3760, 3761, 3761.1, 3762, 3763,
3764, 3765, 3766 AMEND: 3000,
3075.2, 3768.2, 3768.3
08/14/14 ADOPT: 1830.1, 1840.1, 1847.1, 1848.5,
1849.1, 1850.1 AMEND: 1800, 1806,
1812, 1814, 1830, 1831, 1840, 1847,
1848, 1849, 1850, 1851, 1852, 1853,
1854, 1856, 1860, 1866, 1867, 1868,
1870, 1872, 1876, 1878, 1888, 1890,
1892 REPEAL: 1857
07/22/14 AMEND: 3044, 3190, 3315
07/17/14 ADOPT: 3620, 3621, 3622, 3623, 3624,
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