



# California Regulatory Notice Register

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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 2. CALIFORNIA PUBLIC EMPLOYEES' RETIREMENT SYSTEM**

**Division 1. Administrative Personnel  
Chapter 2. Board of Administration of Public Employees' Retirement System**

NOTICE IS HEREBY GIVEN that the Board of Administration (Board) of the California Public Employees' Retirement System (CalPERS) proposes to take the regulatory action described below in the Informative Digest after considering public comments, objections, or recommendations regarding the proposed regulatory action.

**I. PROPOSED REGULATORY ACTION**

In this filing, the Board proposes to add the following Section to Article 2 of Subchapter 1, Chapter 2 of Division 1 of Title 2 of the California Code of Regulations (CCR).

- **Section 555.5, Accrual of Interest on Certain Delayed Payments.**

By proposing this regulation, CalPERS seeks to (1) define the circumstances under which interest should be included in retroactive payments to participants of a defined benefit plan administered by the CalPERS Board, (2) establish what interest rate should apply, and (3) establish a fair administrative appeal process for participants to pursue claims that a defined benefit plan has failed to pay interest when required under the regulation. The proposed regulation is consistent with existing law and is reasonably necessary for the efficient and effective administration of the defined benefit plans administered by the CalPERS Board.

**II. WRITTEN COMMENT PERIOD**

Any interested person may submit written comments relevant to the proposed regulatory action. The written comment period has been established commencing on

**May 8, 2015** and closing on **June 22, 2015** at 5:00 p.m. The Regulation Coordinator must **receive** all written comments by the close of the comment period. Comments may be submitted via fax at (916) 795-4607; E-mailed to [Regulation\\_coordinator@calpers.ca.gov](mailto:Regulation_coordinator@calpers.ca.gov); or mailed to the following address:

Anthony Martin, Regulation Coordinator  
California Public Employees' Retirement System  
P.O. Box 942702  
Sacramento, CA 94229-2702  
Phone: (916) 795-3038

**III. PUBLIC HEARING**

A public hearing will be held before the CalPERS Finance and Administration Committee at the time, date and location listed below.

**NOTICE THAT A PUBLIC HEARING IS SCHEDULED**

**Tuesday, August 18, 2015**

Beginning at 9:00 a.m.  
CalPERS Auditorium, Lincoln Plaza North  
400 Q Street  
Sacramento, CA 95811

**IV. ACCESS TO HEARING ROOM**

The CalPERS Auditorium will be accessible to persons with mobility impairments, and it can be made accessible to persons with hearing or visual impairments upon advance request to the CalPERS Regulation Coordinator.

**V. AUTHORITY AND REFERENCE**

The Board's authority to add the proposed regulation to the CCR derives from the Board's plenary authority and fiduciary responsibility over the assets of the public retirement system and exclusive responsibility to administer the Plans in a manner that will assure prompt delivery of benefits and related services to the members and their beneficiaries, pursuant to the California Constitution (Section 17 of Article XVI) and in accordance with the California Government Code Sections 20120-20121.

Reference citations: California Government Code Sections 9353, 20120, 20121, 20134, 20160, 75005, and 75505.

**INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

Government Code section 20160(b) requires the board to "correct all actions taken as a result of errors or

omissions of . . . this system.” Section 20160(e), generally requires such corrections to be made so that “the status, rights, and obligations of all parties . . . are adjusted to be the same that they would have been if the act that would have been taken, but for the error or omission, was taken at the proper time . . .” Additionally, case law (*see Olson v. Cory* (1983) 35 Cal.3d 390) holds that prejudgment interest applies to pension payments that are owed to participants, but which have been “wrongfully withheld.” The proposed regulation is consistent with current law, and it is intended to define the circumstances under which interest should be included in retroactive payments to participants of a defined benefit plan administered by the CalPERS Board by drawing a distinction between ordinary administrative processing time and “wrongfully withheld” payments, as those concepts reasonably apply to the defined benefit plans administered by the Board.

Specifically, the proposed regulation establishes 90 days as a reasonable administrative processing time for retroactive payments to participants of a defined benefit plan. That 90 days would not start running until (1) the right to the payment has accrued, and (2) the defined benefit plan has all of the information it needs to determine the proper amount of the payment.

The proposed regulation establishes a seven percent per annum simple (non-compounding) interest rate as the appropriate interest rate for delayed payments. This is the default interest rate established by Article XV, Section 1 of the California Constitution.

The proposed regulation specifies a process for participants to pursue claims that a defined benefit plan has failed to pay interest when required by the regulation.

The regulation makes use of the Board’s existing administrative appeal procedures under Board Regulation 555, *et seq.*, to ensure that there is a fair process available to participants who believe they have been denied interest owing to them.

The proposed regulation delegates authority to the CalPERS Executive Officer or his or her designee to grant a participant’s claim for interest under this regulation for \$2,000 or less, if the Executive Officer or his or her designee determines that the claim has merit.

The proposed regulation specifies that a participant must make a claim for interest under this regulation within three years of receiving the payment that the participant claims should have included interest.

**Consistency/Compatibility with Existing Regulations**

CalPERS evaluated whether there were any other laws or state regulations concerning the accrual of interest to participants on delayed payments and has concluded that this is the only applicable regulation on the matter. Therefore, the proposed regulation is not incon-

sistent or incompatible with existing law or existing state regulations.

**Anticipated Benefit**

The primary benefit of approving the proposed regulatory action is that it will provide clear and transparent guidelines for CalPERS staff and participants of defined benefit plans administered by the CalPERS Board. Further, it should help resolve legal disputes with participants claiming entitlement to interest.

**Pre-notice Consultation with the Public**

No pre-notice consultation was done with the public, as the proposed regulation does not involve complex proposals or a large number of proposals that cannot easily be reviewed during the comment period.

VI. EFFECT ON SMALL BUSINESS

The proposed regulatory action does not affect small business because it applies only to participants of the defined benefit plans administered by the CalPERS Board.

VII. DISCLOSURES REGARDING THE PROPOSED REGULATORY ACTION

- A. MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS: The proposed regulatory action does not impose any mandates on local agencies and school districts.
- B. COSTS OR SAVINGS TO ANY STATE AGENCY: The fiscal impact of the proposed regulation is difficult to quantify, but likely minimal. The proposed regulation would result in interest payments on some payments that are made to participants that would not otherwise be made. The instances in which payments would be subject to the accrual of interest should be rare, however, as the vast majority of all participant payments that would be subject to the regulation are made within the time frames contemplated by the proposed regulation. Further, the additional costs associated with the regulation may be offset by the savings resulting from the efficiency and predictability that the regulation would bring to the defined benefit plans administered by the Board.
- C. COSTS TO ANY LOCAL AGENCY OR SCHOOL DISTRICT: The proposed regulatory action will not result in any costs on any local agency or school district.
- D. NONDISCRETIONARY COSTS OR SAVINGS IMPOSED ON LOCAL AGENCIES: The proposed regulatory action does not impose any

nondiscretionary costs or savings on local agencies.

- E. **COSTS OR SAVINGS IN FEDERAL FUNDING TO THE STATE:** The proposed regulatory action will not result in additional costs or savings in federal funding to the State.
- F. **ADVERSE ECONOMIC IMPACT:** The proposed regulatory action 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.
- G. **COST IMPACT ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES:** CalPERS is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed regulatory action.
- H. **RESULTS OF THE ECONOMIC IMPACT ANALYSIS:** The proposed regulatory action: (1) will not create or eliminate jobs within California; (2) will not create new businesses or eliminate existing businesses within California; (3) will not affect the expansion of businesses currently doing business within California; and (4) will benefit the health and welfare of California residents by ensuring that the CalPERS defined benefit plans are administered under clear and transparent guidelines for the processing of claims for the payment of interest.
- I. **EFFECT ON HOUSING COST:** The proposed regulatory action has no effect on housing costs.
- J. **COSTS TO ANY LOCAL AGENCY OR SCHOOL DISTRICT WHICH MUST BE REIMBURSED IN ACCORDANCE WITH GOVERNMENT CODE SECTIONS 17500 THROUGH 17630:** There are no costs to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630.

#### VIII. CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(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 regulatory action is proposed, or would be as effective as, and less burdensome to, affected private persons than the proposed action, or would be more cost-effective to affected private per-

sons and equally effective in implementing the statutory policy or other provision of law.

In some situations, statutory law provides clear direction as to when interest should be paid to defined benefit plan participants, and which interest rate should be used. For example, Government Code section 20178 provides that the Board shall credit all contributions of members in the retirement fund (which are sometimes refunded to the member) with interest at an interest rate of 6 percent compounded at each June 30. As another example, Government Code section 21499 provides for interest accrual on death benefits under certain circumstances. In many situations, however, statutory law does not provide clear direction as to when interest should be paid and at what rate. CalPERS has determined that the proposed regulation is the most efficient and effective means of establishing guidelines governing the payment of interest to participants in defined benefit plans. No other reasonable alternative has been brought to the attention of the Board. Nevertheless, the Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation during the written comment period.

#### IX. CONTACT PERSON

Please direct inquiries concerning the proposed regulatory action to:

Anthony Martin, Regulation Coordinator  
 California Public Employees' Retirement System  
 P.O. Box 942702  
 Sacramento, CA 94229-2702  
 Phone: (916) 795-3038

The backup contact for these inquiries is:

Christina Nutley, Regulation Coordinator  
 California Public Employees' Retirement System  
 P.O. Box 942702  
 Sacramento, CA 94229-2702  
 Phone: (916) 795-3038

Please direct requests concerning the copies of the proposed text (the "express terms") of the regulation, the Initial Statement of Reasons, the modified text of the regulation, if any, or other information about processing of this regulatory action to Anthony Martin, Regulation Coordinator, at [Regulation\\_coordinator@calpers.ca.gov](mailto:Regulation_coordinator@calpers.ca.gov).

#### X. AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION, AND RULEMAKING FILE

The entire rulemaking file is available for public inspection through the Regulation Coordinator at the ad-

dress shown in section II. To date, the file consists of this Notice, the proposed text of the regulation, the Initial Statement of Reasons, the Economic Impact Assessment, the Economic and Fiscal Impact Statement, and a letter dated April 21, 2015 from John Michael Jensen. A copy of the proposed text, the Initial Statement of Reasons, the Economic Impact Assessment, the Economic and Fiscal Impact Statement, and the letter dated April 21, 2015 from John Michael Jensen is available at no charge upon telephone or written request to the Regulation Coordinator.

For immediate access, the regulatory material regarding this action can be accessed at CalPERS' website at [www.calpers.ca.gov](http://www.calpers.ca.gov).

**XI. AVAILABILITY OF CHANGED OR MODIFIED TEXT**

The Board may, on its own motion or at the recommendation of any interested person, modify the proposed text of the regulation after the public comment period closes.

If the Board modifies its regulatory action, it will prepare a comparison of the original proposed text and the modifications for an additional public comment period of not less than 15 days prior to the date on which the Board adopts, amends, or repeals the resulting regulation. A copy of the comparison text will be mailed to all persons who submitted written or oral comments or asked to be kept informed as to the outcome of this regulatory action.

**XII. AVAILABILITY OF THE FINAL STATEMENT OF REASONS**

The Final Statement of Reasons can be obtained, once it has been prepared, by written request to Anthony Martin, Regulation Coordinator, at the address shown above in Section II.

**TITLE 2. FAIR POLITICAL PRACTICES COMMISSION**

NOTICE IS HEREBY GIVEN that the Fair Political Practices Commission (Commission), pursuant to the authority vested in it by Sections 82011, 87303, and 87304 of the Government Code to review proposed conflict-of-interest codes, will review the proposed/amended conflict-of-interest codes of the following:

**CONFLICT-OF-INTEREST CODES**

**ADOPTION**

**MULTI-COUNTY:** Antelope Valley Resource Conservation District

A written comment period has been established commencing on May 8, 2015, and closing on **June 22, 2015**. Written comments should be directed to the Fair Political Practices Commission, Attention Ivy Branaman, 428 J Street, Suite 620, Sacramento, California 95814.

At the end of the 45-day comment period, the proposed conflict-of-interest code(s) will be submitted to the Commission's Executive Director for her review, unless any interested person or his/her duly authorized representative requests, no later than 15 days prior to the close of the written comment period, a public hearing before the full Commission. If a public hearing is requested, the proposed code(s) will be submitted to the Commission for review.

The Executive Director of the Commission will review the above-referenced conflict-of-interest code(s), proposed pursuant to Government Code Section 87300, which designate, pursuant to Government Code Section 87302, employees who must disclose certain investments, interests in real property and income.

Any interested person may present statements, arguments or comments, in writing to the Executive Director of the Commission, relative to review of the proposed conflict-of-interest code(s). Any written comments must be received no later than **June 22, 2015**. If a public hearing is to be held, oral comments may be presented to the Commission at the hearing.

**COST TO LOCAL AGENCIES**

There shall be no reimbursement for any new or increased costs to local government which may result from compliance with these codes because these are not new programs mandated on local agencies by the codes since the requirements described herein were mandated by the Political Reform Act of 1974. Therefore, they are not "costs mandated by the state" as defined in Government Code Section 17514.

**EFFECT ON HOUSING COSTS AND BUSINESSES**

Compliance with the codes has no potential effect on housing costs or on private persons, businesses or small businesses.

**AUTHORITY**

Government Code Sections 82011, 87303 and 87304 provide that the Fair Political Practices Commission as

the code-reviewing body for the above conflict-of-interest codes shall approve codes as submitted, revise the proposed code and approve it as revised, or return the proposed code for revision and re-submission.

REFERENCE

Government Code Sections 87300 and 87306 provide that agencies shall adopt and promulgate conflict-of-interest codes pursuant to the Political Reform Act and amend their codes when change is necessitated by changed circumstances.

CONTACT

Any inquiries concerning the proposed conflict-of-interest code(s) should be made to Ivy Branaman, Fair Political Practices Commission, 428 J Street, Suite 620, Sacramento, California 95814, telephone (916) 322-5660.

AVAILABILITY OF PROPOSED CONFLICT-OF-INTEREST CODES

Copies of the proposed conflict-of-interest codes may be obtained from the Commission offices or the respective agency. Requests for copies from the Commission should be made to Ivy Branaman, Fair Political Practices Commission, 428 J Street, Suite 620, Sacramento, California 95814, telephone (916) 322-5660.

**TITLE 4. CALIFORNIA HORSE RACING BOARD**

NOTICE OF PROPOSAL TO AMEND RULE 1433, APPLICATION FOR LICENSE TO CONDUCT A HORSE RACING MEETING

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

PROPOSED REGULATORY ACTION

The Board proposes to amend Board Rule 1433, Application for License to Conduct a Horse Racing Meeting. The proposed amendment to Rule 1433 will modify the text of the regulation, as well as the Application for License to Conduct a Horse Racing Meeting, CHRB-17 (Rev. 07/11) (CHRB-17), and Application for License to Conduct a Horse Racing Meeting of a

California Fair, CHRB-18 (Rev. 07/11) (CHRB-18), which are incorporated by reference into Rule 1433. The proposed amendment to Rule 1433 will delete subsection (b) which requires any thoroughbred racing association that operates four weeks or more of continuous thoroughbred racing in a calendar year to install a polymer synthetic racing surface. The proposed amendment to Rule 1433 will also revise the forms CHRB-17, and CHRB-18 to collect information on stakes races for the prior two race meetings; collect the name, emergency telephone number and hours of the racing veterinarian onsite during training hours, workouts and during racing; collect information on the proposed offering of any pari-mutuel wagers that were not listed in the prior year's pari-mutuel wagering program; and capture the takeout percentage for each type of wager.

PUBLIC HEARING

The Board will hold a public hearing starting at **9:30 a.m., Thursday, June 25, 2015**, or as soon after that as business before the Board will permit, at the **Los Alamitos Race Course, 4961 E. Katella Avenue, Los Alamitos, 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 June 22, 2015**. The Board must receive all comments at that time; however, written comments may still be submitted at the public hearing. Submit comments to:

Harold Coburn, Regulation Analyst  
California Horse Racing Board  
1010 Hurley Way, Suite 300  
Sacramento, CA 95825  
Telephone (916) 263-6026  
Fax: (916) 263-6022  
E-Mail: haroldc@chrh.ca.gov

AUTHORITY AND REFERENCE

Authority cited: Sections 19420 and 19440, Business and Professions Code. Reference: Sections 19440, 19480, 19481 and 19562, Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT  
OVERVIEW

Business and Professions Code section 19420 provides that the Board shall have jurisdiction and supervision over meetings in this State where horse races with wagering on their results are held or conducted, and over all persons or things having to do with the operation of such meetings. Business and Professions Code section 19440 provides that the Board shall have all powers necessary and proper to enable it to carry out fully and effectually the purpose of this chapter. Responsibilities of the Board shall include, but are not limited to, adopting rules and regulations for the protection of the public and the control of horse racing and pari-mutuel wagering. Business and Professions Code section 19480 states the Board may issue to any person who makes application in writing, who has complied with the provisions of horse racing law, a license to conduct a horse racing meeting at the track specified in the application; provided, the Board determines that the issuance will be in the public interest. Business and Professions Code section 19481 provides that in performing its responsibilities, the Board shall establish safety standards governing equipment for horse and rider. Business and Professions Code section 19562 states the Board may prescribe rules, regulations, and conditions, consistent with the provisions of this chapter, under which all horse races with wagering on their results shall be conducted in this State.

The proposed amendment to Rule 1433 will delete subsection (b) to remove the requirement that any thoroughbred racing association that operates four weeks or more of continuous thoroughbred racing in a calendar year must install a polymer synthetic racing surface. The requirement for polymer synthetic racing surfaces became effective in January 2007. When the Board first considered requiring thoroughbred race meet operators to install synthetic tracks it was believed synthetic surfaces would improve safety and prevent catastrophic injuries to horses. Another reason for adopting the requirement for synthetic racing surfaces was the promise of decreased maintenance and renovation costs. Synthetic tracks were considered low maintenance, requiring little to no watering, with consistent performance. However, critics of the tracks maintain that while synthetic surfaces have resulted in the reduction of serious concussion injuries to horses, the incidence of muscle and soft tissue injuries have increased. Additionally, synthetic racing surfaces have proven to require constant maintenance. Regularly scheduled refurbishment of wax and fiber is required to maintain the original material properties of synthetic racing surfaces to ensure safe operation. Synthetic racing surface performance has proven to be significantly affected by ambi-

ent temperature. This has resulted in the need for added harrowing and watering operations to control critical material properties. In 2010, after experiencing problems over a number of years with its synthetic racing surface, the Los Angeles Turf Club petitioned the Board for an exemption from the requirements of subsection 1433(b) and converted its synthetic track back to a dirt race surface. Hollywood Park Race Track, which had a synthetic racing surface, closed in December 2013. At the March 2014 Regular Board meeting, Del Mar Thoroughbred Club (Del Mar) announced plans to seek an exemption to subsection 1433(b), and to replace its synthetic track with a dirt track in time for its 2015 summer racing season. Currently, only Golden Gate Fields in Northern California has a synthetic racing surface. Given these circumstances, the Board has determined that Rule 1433 should be amended to delete subsection 1433(b). The proposed amendment to Rule 1433 will not prevent a thoroughbred racetrack from installing a synthetic surface; instead, it will allow thoroughbred racing associations to determine what type of track surface best suits their circumstances.

Rule 1433 incorporates by reference the forms CHRB-17 and CHRB-18; therefore, any revisions to the application forms would necessitate an amendment of Rule 1433.

The forms Application for License to Conduct a Horse Racing Meeting, CHRB-17 (Rev. 02/15) (CHRB-17), and Application for License to Conduct a Horse Racing Meeting of a California Fair, CHRB-18 (Rev. 02/15) (CHRB-18), are incorporated by reference into Rule 1433, as it would be cumbersome, unduly expensive or otherwise impractical to publish the documents in the California Code of Regulations.

Proposed changes to form CHRB-17 include:

**Section 3, D1, Racing Program:** This section of the CHRB-17 has been added to capture information regarding stakes races the applicant association offered during its past two race meetings. Information on stakes races that the applicant association intends to offer is collected on the form CHRB-17; however, information concerning past stakes races is not captured. The information collected will allow the Board to compare the stakes schedule the applicant association intends to offer with those it offered during its past two race meetings. This gives the Board a mechanism to track the status of the applicant's graded stakes races over time to ensure the quality of California's stakes races is sustained. If a stakes race is modified in any way, the Thoroughbred Owners and Breeders of America (TOBA) American Graded Stakes Committee (GSC) could eliminate it as a California stakes race.

**Section 3, D2, Racing Program:** Section 3, D2 of the CHRB-17 has been added to capture information regarding stakes races that have been added, or are new

for the current race meeting and details regarding any alterations to the identified stakes races. An association's added stakes races may not be new races to the industry. When Hollywood Park Race Track closed in December 2013, Los Alamitos Race Course added stakes races previously run by Hollywood Park. New stakes races may be races previously run by the applicant association that have met the GSC criteria for grading. The Board is interested in details regarding changes to stakes races, such as age, sex, eligibility, purse or calendar changes, as modifications to stakes races could result in a review by the GSC and a change in the grade of the race, or elimination of its grading. Changes in grade, or the elimination of stakes races could affect the quality of horses that run at the race meeting. A racing association wants to attract quality race horses, as a higher level of racing results in greater interest on the part of racing fans. The addition of subsection 3, D2 provides the Board with a mechanism to track the status of altered, added or new graded stakes races in California.

**Section 3, D3, Racing Program:** This section of the CHRB-17 has been added to capture information regarding stakes races that have been dropped or deleted and the reason for the change. A race may be dropped by the applicant racing association if there are not enough entrants. Races may be deleted due to decisions made by the racing association or by the GSC. The Board is interested in this information, as the elimination of a stakes race may affect the quality of horses that run at the race meeting, and may lower fan interest.

Stakes races are also known as "graded stakes" and are "higher-class" races for larger purses, as opposed to overnight or claiming races. There are three grades to a graded stakes race. The grade assigned a race is controlled by the GSC, which is a committee of the TOBA, a national thoroughbred horse racing organization. The GSC ensures a Grade 1, 2, or 3 stakes race is the same class level irrespective of where it is run. The purses for graded stakes races are generally higher and the graded stakes races attract better quality horses, this in turn may result in increased attendance and wagering. Race-tracks benefit from having their races graded. The GSC criteria for grading a stakes race provides if a graded or eligible race is altered materially in age, sex, eligibility, racetrack location, or purse, or is substantially changed on the calendar (60 or more days), this will prompt a review and may result in a change in grade. A new race must be run two years before it can be considered for grading. If a race is not run for two or more years or has not run in two of the last three years, it is ineligible for grading. If a race is scheduled to be moved from dirt to turf or vice versa, or if its distance is altered (a) by more than one-quarter mile, or (b) from sprint distance (less than one mile) to route distance (one mile or greater) or

vice versa, it will be considered a new race and is ineligible for grading until run twice under the new conditions. Once a race has been assigned the status of a graded stakes race, the graded race has to meet the GSC requirements to continue its eligibility. If the graded stakes race does not meet the requirements of the GSC its status can be downgraded or it may lose its graded stakes race eligibility. Information on graded stakes races for the prior two race meetings is necessary to provide the Board with a mechanism to track the status of graded stakes races in California to ensure that they are not dropped and lost to future race meetings. The information collected on the prior stakes races will be invaluable in assisting the Board to ensure that California's graded stakes races are not lost or downgraded.

**Section 9, A, Equine Emergency Services:** This is a new subsection within the CHRB-17, which requires the applicant association to provide the name and emergency phone number of the racing veterinarian onsite during training hours, workouts and during racing. This information must be provided for the racetrack and any auxiliary sites. Collecting the contact information for the veterinarian available for emergency services will ensure that Board staff will have such information available, if needed.

**Section 9, A1, Equine Emergency Services:** This new subsection within the CHRB-17 requires the applicant association to attach a copy of the schedule listing the dates and times that the racing veterinarian will be available onsite during training hours, workouts and during racing. This information must be provided for the racetrack and any auxiliary sites. Collecting the work schedule for the veterinarian available for emergency services will ensure that Board staff will have such information available, if needed.

The name of the racing veterinarian, the emergency telephone number and the hours he or she is onsite during training hours, workouts and during racing is not currently captured on the form CHRB-17. Capturing the name, emergency telephone number and hours of the onsite veterinarian is necessary to provide the Board with information regarding who will be available to treat a horse during training hours, and workouts, and racing at the race track and auxiliary sites. The auxiliary sites are facilities used to stable the overflow of horses when the association track does not have enough stalls to accommodate the horse population for the race meeting. When horses are stabled at an auxiliary site, training and workouts for those horses usually occur at the auxiliary; therefore, it is necessary to collect a schedule of availability for the racing veterinarian for both the association and auxiliary site. The racing veterinarian has the authority to treat any horse in event of an emergency, accident or injury, and is authorized to euthanize any horse which in the veterinarian's opinion is so seri-

ously injured that such action is necessary. Obtaining the veterinarian's contact information and work schedule will identify the responsible individual(s), and will ensure that Board staff will have such information available, if needed.

**Section 10, B, Pari-Mutuel Wagering Program:** This section of the CHRB-17 has been modified to collect information regarding the applicant association's proposed offering of pari-mutuel wagers that were not offered in the prior year's pari-mutuel wagering program, or regarding pari-mutuel wagers that are not being carried forward from the previous year's wagering program. This information is not currently collected. Capturing information on the current year's proposed pari-mutuel wagers versus the prior year will allow the Board to make a year to year comparison to be aware of changes in the applicant association's wagering program, as they occur.

**Section 10, G, Pari-Mutuel Wagering Program:** This section of the CHRB-17 has been modified to capture the takeout percentage for each type of pari-mutuel wager listed on the race meet application. Pari-mutuel wagering information is currently collected on the form CHRB-17; however, the takeout percentage for each type of wager is not captured. Takeout is the source of all pari-mutual revenues for the industry. Take-out rates are set by State law and they vary by type of wager and breed. To ensure the Board is informed, the CHRB-17 will be amended to include the takeout rates for each type of wager. Capturing the takeout percentage for each type of wager on the race meet application is necessary to provide the Board with complete information regarding the applicant's pari-mutuel wagering program. The amendment provides the Board with a record of the takeout percentage for each type of wager.

**Section 16, A, Emergency Services:** This section of the CHRB-17 has been amended to change the phrase "the running of the races" to "during racing" for the purpose of consistency. This phrase is also used in section 9, Equine Emergency Services.

Proposed changes to form CHRB-18 include:

**Section 3, E1, Racing Program:** This section of the CHRB-18 has been added to capture information regarding stakes races for the past two race meetings. Such information will provide the Board with the ability to compare the applicant racing fair's proposed stakes schedule with its previous year's stakes. This will keep the Board abreast of the status of graded stakes races in California to ensure the races are maintained from year to year, and that the quality of California stakes races is sustained. If a stakes race is not run, or modified in any way, the race could be eliminated by the GSC as a California stakes race.

**Section 3, E2, Racing Program:** This section of the CHRB-18 has been added to capture information re-

garding stakes races that have been altered, added, or are new for the current race meeting. The Board is interested in details regarding changes to stakes races, such as age, sex, eligibility, purse or calendar changes, as modifications to stakes races could result in a review by the GSC and a change in the grade of the race, or elimination of its grading. Changes in grade, or the elimination of stakes races could affect the quality of horses that run at the fair's race meeting. Such changes also affect fan interest. The information provided under Section 3, E2 allows the Board to track the status of graded stakes races in California to ensure the quality of California stakes races is sustained.

**Section 3, E3, Racing Program:** This section of the CHRB-18 has been added to capture information regarding stakes races that have been dropped or deleted, and the reason for the change. A race may be dropped by the applicant racing fair association if there are not enough entrants. Races may be deleted due to decisions made by the racing fair association or by the GCS. The Board is interested in this information, as the elimination of a stakes race may have a detrimental effect on the quality of horses that run at the race meeting, and may lower fan interest. The proposed change provides the Board with a mechanism to track the status of graded stakes races in California to ensure the quality of California stakes races is sustained.

**Section 9, A, Equine Emergency Services:** This is a new subsection within the CHRB-18, which requires the applicant racing fair association to provide the name and emergency phone number of the racing veterinarian onsite during training hours, workouts and during racing. This information must be provided for the racetrack and any auxiliary sites. Collecting the contact information for the veterinarian available for emergency services will ensure that Board staff will have such information available, if needed.

**Section 9, A1, Equine Emergency Services:** This new subsection within the CHRB-18 requires the applicant racing fair association to attach a copy of the schedule listing the dates and times that the racing veterinarian will be available onsite during training hours, workouts and during racing. This information must be provided for the racetrack and any auxiliary sites. Collecting the work schedule for the veterinarian available for emergency services will ensure that Board staff will have such information available, if needed.

The name of the racing veterinarian, the emergency telephone number and the hours he or she is onsite during training hours, workouts and during racing is not currently captured on the form CHRB-18. Capturing the name, emergency telephone number and hours of the onsite veterinarian is necessary to provide the Board with information regarding who will be available to treat a horse during training hours, and workouts, and

racing at the race track and auxiliary sites. The auxiliary sites are facilities used to stable the overflow of horses when the racing fair's track does not have enough stalls to accommodate the horse population for the race meeting. When horses are stabled at an auxiliary site, training and workouts for those horses usually occur at the auxiliary; therefore, it is necessary to collect a schedule of availability for the racing veterinarian for both the racing fair and auxiliary site. The racing veterinarian has the authority to treat any horse in event of an emergency, accident or injury, and is authorized to euthanize any horse which in the veterinarian's opinion is so seriously injured that such action is necessary. Obtaining the veterinarian's contact information and work schedule will identify the responsible individual(s), and will ensure that Board staff will have such information available, if needed.

**Section 10, C, Pari-Mutuel Wagering Program:** This section of the CHRB-18 has been modified to collect information regarding the proposed offering of pari-mutuel wagers that were not offered in the prior year's pari-mutuel wagering program, or regarding pari-mutuel wagers that are not being carried forward from the previous year's wagering program. This information is not currently collected. Capturing information on the current year's proposed pari-mutuel wagers versus the prior year will allow the Board to make a year to year comparison to be aware of changes in the applicant association's wagering program, as they occur.

**Section 10, H, Pari-Mutuel Wagering Program:** This section of the CHRB-18 has been modified to capture the takeout percentage for each type of pari-mutuel wager listed on the fair's race meet application. Pari-mutuel wagering information is currently collected on the form CHRB-18; however, the takeout percentage for each type of wager is not captured. To ensure the Board is informed, the CHRB-18 will be amended to include the takeout rates for each type of wager. Capturing the takeout percentage for each type of wager on the race meet application is necessary to provide the Board with complete information regarding the applicant's pari-mutuel wagering program. The amendment provides the Board with a record of the takeout percentage for each type of wager.

**Section 15, A, Emergency Services:** This section of the CHRB-18 has been amended to change the phrase "the running of the races" to "during racing" for the purpose of consistency. This phrase is also used in section 9, Equine Emergency Services.

All other changes to the forms CHRB-17 and CHRB-18 are for the purpose of clarification, consistency, renumbering and grammar.

POLICY STATEMENT OVERVIEW OF ANTICIPATED BENEFITS OF PROPOSAL

The proposed amendment to Rule 1433 will delete the mandate for a polymer synthetic track surface imposed on certain thoroughbred racetracks, and help the Board make a more informed decision when it considers race meet applications.

The proposed amendment to Rule 1433 subsection (b) will delete the requirement that specified thoroughbred racing associations install a polymer synthetic racing surface. Rather than dictate a "one size fits all" racing surface, the proposed amendment benefits the industry by removing the mandate, which will allow California's thoroughbred racing associations to determine for themselves what type of track surface best suits their circumstances.

The proposed amendment to Rule 1433 will revise the forms CHRB-17 and CHRB-18 to collect information on the applicant association's stakes races for the prior two race meetings, as well as altered, new or deleted stakes; collect the name and emergency telephone number of the racing veterinarian and the hours he or she is onsite during training hours, workouts and during racing; collect information on the proposed offering of any pari-mutuel wagers that were not listed in the prior year's pari-mutuel wagering program, or wagers that are not being carried over from the previous year; and capture the takeout percentage for each type of wager.

Collecting information on the previous year's graded stakes races, as well as altered, new or deleted stakes, has the benefit of providing the Board with a mechanism to compare and track the quality of graded stakes races in California. It is important that graded stakes are maintained year-to-year; such races attract a higher quality of horses, and increase public participation in this State's race meetings. When considering race meet applications, the Board needs to be fully informed so that it can assure California will continue to operate successful race meetings, and offer world-class thoroughbred racing.

Capturing the name of the racing veterinarian, the racing veterinarian's emergency telephone number, and the hours he or she will be onsite at the racetrack and auxiliary sites, will provide the Board with information regarding who will be available to treat a horse during training hours, workouts and running of the race. The racing veterinarian has the authority to treat any horse in event of an emergency, accident or injury, and he or she is authorized to euthanize any horse which in his or her opinion is so seriously injured that it is in the best interest of racing to take such action. The collection of the

veterinarian's emergency contact information and work schedule will have the benefit of assisting staff in its communication with the veterinarian, if needed.

Pari-mutuel wagering information is currently collected on the race meet application forms CHRB-17 and CHRB-18; however, the takeout percentage for each type of wager is not captured. To ensure the Board is informed, the CHRB-17 and CHRB-18 will be amended to include takeout rates for each type of wager. Capturing the takeout percentage for each type of wager on the race meet application benefits the Board, as it will be fully informed in its consideration of race meet applications.

Consistency with Existing State Regulations: During the process of developing the proposed amendment, the Board has conducted an evaluation for any related regulations and has determined that Rule 1433 is the only regulation dealing with applications for license to conduct a horse racing meeting. Therefore the proposed regulation is neither inconsistent nor incompatible with existing state regulations.

#### DISCLOSURE REGARDING THE PROPOSED ACTION

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 Sections 17500 through 17630: none.

Other non-discretionary costs 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 1433 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.

#### RESULT OF ECONOMIC IMPACT ANALYSIS

The adoption of the proposed amendment to Rule 1433 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 amendment to Rule 1433 promotes public awareness, and horse health and safety. The proposed amendment to Rule 1433 subsection (b) will remove the requirement for the use of a polymer synthetic racing surface. The proposed amendment to Rule 1433 will also revise the forms CHRB-17 and CHRB-18 to collect information on stakes races for the prior two race meetings; collect the name, emergency telephone number, and hours of the racing veterinarian onsite during the training hours, workouts and during racing; collect information on the proposed offering of any pari-mutuel wagers that were not listed in the prior year's pari-mutuel wagering program; and capture the takeout percentage for each type of wager. The proposed amendment to Rule 1433 eliminates the mandate for the use of a polymer synthetic racing surface, which will provide cost savings to thoroughbred racing associations. The proposed amendment to Rule 1433 subsection (b) will remove the absolute requirement for the use of a polymer synthetic racing surface at all facilities that conduct continuous thoroughbred horse racing for four weeks or more in a calendar year. The amendment will not prevent a racetrack from installing a synthetic surface; instead it will allow thoroughbred racing associations to determine what type of track surface best suits their circumstances. Capturing information on graded stakes races for the prior two race meetings is necessary to provide the Board with a mechanism to track the status of graded stakes races in California to ensure that they are not dropped and lost to future race meetings. The information collected on the prior stakes races will be invaluable to assist the Board with ensuring that quality of the California graded stakes do not decrease. Capturing the name, emergency telephone number and hours of the onsite veterinarian will provide the Board with information on who will be available to treat a horse during training hours, workouts and running of race for the association and auxiliary training sites. The contact information and work schedule of the veterinarian available for emergency services will assist staff in communicating with the racing veterinarian, if needed. Collecting information on the proposed offering of any pari-mutuel wagers that were not listed in the prior year's pari-mutuel wagering program, or that are not being carried forward from the previous year's pari-mutuel wagering program will allow the Board to make a comparison from year to year and ensure that the wagering options do not decrease.

Effect on small businesses: none. The proposal to amend Rule 1433 does not affect small businesses because horse racing is not a small business 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 PERSON

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:

Harold Coburn, Regulation Analyst  
 California Horse Racing Board  
 1010 Hurley Way, Suite 300  
 Sacramento, CA 95825  
 Telephone: (916) 263-6026  
 E-mail: haroldc@chrb.ca.gov

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

Andrea Ogden,  
 Policy, Regulations and Legislation  
 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 may be obtained by contacting Harold Coburn, or the alternative 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 regulations should be sent to the attention of Harold Coburn 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 Harold Coburn 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 web site. The rulemaking file consists of the notice, the proposed text of the regulation and the initial statement of reasons. The Board's website address is: [www.chrb.ca.gov](http://www.chrb.ca.gov).

**TITLE 15. CALIFORNIA PRISON INDUSTRY AUTHORITY**

**NOTICE IS HEREBY GIVEN** that the California Prison Industry Authority (CALPIA) and the Prison Industry Board (PIB) pursuant to the authority granted by Penal Code (PC) Sections 2801 and 2809 in order to implement, interpret and make specific Penal Code Sections 2801 and 2809, propose to adopt Sections 8115, 8116, 8116.1, and 8117 of Article 6, Chapter 1, of the California Code of Regulations (CCR), Title 15, Division 8 CALPIA concerning Personnel.

PUBLIC HEARING

**At this time, no public hearing has been scheduled concerning the proposed change to regulations. Anyone may request a public hearing by contacting the Contact Person set forth below. Requests for public hearings must be made no later than June 6, 2015.**

PUBLIC COMMENT PERIOD

The public comment period will close **June 22, 2015 at 5:00 p.m.** Any person may submit public comments regarding the proposed changes in writing. To be considered, comments must be received before the close of the comment period. Use one of the following to submit:

**MAIL or HAND DELIVERED**

CALPIA/Legal Services Unit  
560 East Natoma Street  
Folsom, CA 95630

**FAX**

(916) 358-2709

**E-MAIL**

[CALPIAregs@calpia.ca.gov](mailto:CALPIAregs@calpia.ca.gov)

CONTACT PERSON

Please direct any inquiries regarding this action or questions of substance of the proposed regulatory action to:

**Dawn Eger, Legal Analyst**  
**California Prison Industry Authority**  
**560 East Natoma Street, CA 95630**  
**Telephone (916) 358-1711**

In the event the contact person is unavailable, inquiries should be directed to the following back-up person:

**John Chimienti, Assistant to General Counsel**  
**California Prison Industry Authority**  
**560 East Natoma Street, CA 95630**  
**Telephone (916) 358-1711**

AUTHORITY AND REFERENCE

California Prison Industry Authority (CALPIA) and the Prison Industry Board (PIB) pursuant to the authority granted by Penal Code (PC) Sections 2801 and 2809 in order to implement, interpret and make specific Penal Code Sections 2801 and 2809, propose to adopt Sections 8115, 8116, 8116.1, and 8117 of Article 6, Chapter 1, of the California Code of Regulations (CCR), Title 15, Division 8 CALPIA concerning Personnel.

INFORMATIVE DIGEST

POLICY STATEMENT OVERVIEW

CALPIA provides work training programs for the participation and rehabilitation of persons under the jurisdiction of California Department of Corrections and Rehabilitation (CDCR). CALPIA workplaces are located throughout California; the majority existing on institution grounds. Some workplaces are established inside of the institutions' walls as well as on the outside of the institutions' walls and on other properties that are not on prison grounds. All CALPIA workplaces create an environment where CALPIA employees are required to work closely with persons under the jurisdiction of CDCR. Because of the close interactions between CALPIA employees and persons under the jurisdiction of CDCR, these regulations are crucial and necessary to support the safety of every person on institution grounds or other locations where persons under the jurisdiction of CDCR are present. Safety is a very serious obligation to maintain within CALPIA workplaces. Without a safe working environment, CALPIA will be unable to implement PC Section 2801 and carry out its productivity goals.

Pursuant to PC Section 2809, CALPIA employees work under a hiring authority which is separate and distinct from the CDCR hiring authority. The challenges of separate hiring authorities require CALPIA to adopt its own personnel rules that are separate from CDCR's. This action is necessary to create similar regulatory requirements as those imposed upon CDCR employees regarding the interactions with persons under the jurisdiction of CDCR. Maintaining similarities will keep CALPIA workplaces safe and consistent for the prison environment.

The policies of the CALPIA will be vetted through the public process of the PIB, as required in PC Section 2808, subsections (h) and (i), and promulgated through the regulatory process as specified in the Administrative Procedure Act (APA). The PIB will review these regulations at the next board meeting held on June 25, 2015. Upon approval, the PIB's Record of Vote and the applicable portion of the meeting minutes will be filed in the rulemaking file. These documents will be filed with the Office of Administrative Law (OAL).

EVALUATION OF  
INCONSISTENCY/INCOMPATIBILITY WITH  
EXISTING REGULATIONS

During the process of developing these regulations and amendments, CALPIA 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.

LOCAL MANDATES

This action imposes no mandates on local agencies or school districts, nor a mandate which requires reimbursement pursuant to Government Code Sections 17500 through 17630.

FISCAL IMPACT STATEMENT

Cost to any local agency or school district that is required to be reimbursed in accordance with Government Code Sections 17500 through 17630:	None.
Cost or savings to any state agency:	None.
Other nondiscretionary cost or savings imposed on local agencies:	None.
Cost or savings in federal funding to the State:	None.

EFFECT ON HOUSING COSTS

The CALPIA has made an initial determination that the proposed action will have no significant effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT ON BUSINESS

The CALPIA has initially determined that the proposed action 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 because they are not affected by CALPIA employees' interactions with persons under the jurisdiction of CDCR.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS/ASSESSMENT

As a result of the economic impact assessment and in accordance with Government Code Section 11346.3(b), the CALPIA has made the following assessments regarding the proposed regulation:

**Creation or Elimination of Jobs within the State of California**

The proposed regulations will not create or eliminate existing jobs within the State of California. It is determined that this action has no significant adverse economic impact on jobs within the State of California because the jobs are not affected by CALPIA employees' interactions with persons under the jurisdiction of

CDCR. The benefits of new, proposed regulations will provide clear and concise personnel rules that will affect CALPIA employees and persons under the jurisdiction of CDCR.

**Creation, Expansion, or Elimination of Existing Businesses (Small or Large) within the State of California**

The proposed regulations will not have an effect on the creation, expansion, or elimination, of small or large businesses within California. It is determined that this action has no significant adverse economic impact on small or large businesses within the State of California because businesses are not affected by CALPIA employees' interactions with persons under the jurisdiction of CDCR. The benefits of new, proposed regulations will provide clear and concise rules that will affect CALPIA employees and persons under the jurisdiction of CDCR.

**Benefits of the Regulations**

The proposed regulatory action will benefit CALPIA employees, CDCR employees, and persons under the jurisdiction of CDCR by providing clear and concise personnel rules that ensure and promote consistency and safety while working with inmates and parolees under the jurisdiction of CDCR.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The CALPIA 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

CALPIA has determined that this action has no adverse impact on small businesses because they are not affected by CALPIA employees' interactions with persons under the jurisdiction of CDCR.

ALTERNATIVES DETERMINATION STATEMENT

CALPIA must determine that no reasonable alternative considered by CALPIA, or that has otherwise been identified and brought to the attention of CALPIA, 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 proposed regulatory action.

Interested persons are invited to present statements or arguments with respect to any alternatives to the changes proposed during the written comment period.

#### AVAILABILITY OF PROPOSED TEXT AND INITIAL STATEMENT OF REASONS

The CALPIA has prepared, and will make available, the text and the Initial Statement of Reasons (ISOR) of the proposed regulations. The rulemaking file for this regulatory action, which contains those items and all information on which the proposal is based (i.e., rulemaking file) is available to the public upon request directed to the CALPIA's contact person. The proposed text, ISOR, and Notice of Proposed Action will also be made available on the CALPIA website <http://www.calpia.ca.gov>.

#### AVAILABILITY OF CHANGES TO PROPOSED TEXT

In the event CALPIA makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the PIB reviews and approves the regulations as revised. CALPIA will accept written comments on the modified regulations for 15 days after the date on which they are made available. Requests for copies of any modified regulation text should be directed to the contact person indicated in this Notice or can be viewed by visiting the CALPIA website <http://www.calpia.ca.gov>.

#### AVAILABILITY OF THE FINAL STATEMENT OF REASONS:

Following its preparation, a copy of the Final Statement of Reasons may be obtained from the CALPIA's contact person or by visiting the CALPIA website <http://www.calpia.ca.gov>.

### 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 June 22, 2015.

Any person interested may present statements or arguments orally or in writing relevant to the action pro-

posed at a hearing to be held at the DCA Headquarters Building Two, 1747 North Market Blvd Ruby Room, Sacramento, CA 95834, on June 25, 2015, at 9:15 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. It also indicated that 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 pharma-

copeial 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 writ-

ten 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 languages 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).

At the July 2014 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 September 05, 2014–October 20, 2014. A regulation hearing was held on November 04, 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 2015 board meeting and online. At the January 2015 board meeting, the board moved to modify the language and notice the modified text for a new comment period. The 15–day comment period ran from February 06, 2015–February 20, 2015.

During the second notice period, the board received many additional written 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 March 2015 board meeting and online. At the March

2015 board meeting, the board moved to modify the language again and notice the new modified text for a new comment period. The second 15–day comment period ran from March 11, 2015–March 25, 2015.

After reviewing and considering all the written and oral comments received, board staff recommended to the board to withdraw the current rulemaking file originally noticed September 04, 2014, and notice the revised language as a new rulemaking. At the April 2015 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 8, 2015.

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 shipping 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) was removed from the regulation for clarity as compounding a commercially available drug preparation is not allowed.
- Subdivision (d) is renumbered to subdivision (c) and 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 “ante-area” for purposes of compounding drug products. The definition clarifies and specifies “ante-area” 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 “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 administration of a compounded drug preparation shall not be begun, the preparation shall not be

dispensed, and the preparation shall not be stored (other than for quarantine purposes).

- Subdivision (c) adds a definition of “biological safety cabinet (BSC)” for purposes of compounding drug products. The definition clarifies and specifies “biological safety cabinet (BSC)” means a ventilated cabinet for compounded sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
- Subdivision (d) adds a definition of “buffer area” for purposes of compounding drug products. The definition clarifies and specifies “buffer area” means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials. 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 may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.
- Subdivision (e) adds a definition of “bulk drug substance” for purposes of compounding drug products. The definition clarifies and specifies “bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate 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” means a physically separate room with walls and doors that provides at least an ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located. A minimum differential positive pressure of 0.02- to 0.05-inch water column is required.
- Subdivision (g) adds a definition of “compounding aseptic isolator (CAI)” for purposes of compounding drug products. The definition clarifies and specifies “compounding aseptic isolator (CAI)” means a form of isolator

specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded.

- Subdivision (h) adds a definition of “compounding aseptic containment isolator (CACI)” for purposes of compounding drug products. The definition clarifies and specifies “compounding aseptic containment isolator (CACI)” means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.
- Subdivision (i) adds a definition of “controlled cold temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled cold temperature” means 2 degrees to 8 degrees C (35.6 degrees to 46.4 degrees F).
- Subdivision (j) 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 (k) 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 (l) adds a definition of “copy or essentially a copy” for purposes of compounding drug products. The definition clarifies and specifies “copy or essentially a copy” means a copy of a commercially available drug product

includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

- Subdivision (m) adds a definition of “daily” for purposes of compounding drug products. The definition clarifies and specifies “daily” means occurring every day that a pharmacy is operating.
- Subdivision (n) adds a definition of “dosage unit” for purposes of compounding drug products. The definition clarifies and specifies “dosage unit” means a quantity sufficient for one administration to one patient, except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit.
- Subdivision (o) is renumbered from previous subdivision (a).
- Subdivision (p) 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 (q) adds a definition of “gloved fingertip sampling” for purposes of compounding drug products. The definition clarifies and specifies “gloved fingertip sampling” means a process whereby compounding personnel lightly press each fingertip and thumb onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.
- Subdivision (r) adds a definition of “hazardous” for purposes of compounding drug products. The definition clarifies and specifies “hazardous” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.
- Subdivision (s) is renumbered from previous subdivision (b). Subdivision (s) amends the definition of “integrity” for the purposes of compounding drug products. The definition clarifies and specifies “integrity” means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions after it is

dispensed. The revised definition removes “retention of potency” and changes “expiration” to “beyond use” as well as changes “noted” to “provided.”

- Subdivision (t) adds a definition of “lot” for purposes of compounding drug products. The definition clarifies and specifies “lot” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).
- Subdivision (u) 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. To be valid, media–fill tests must be conducted on both the most routine and the most challenging compounding procedures performed.
- Subdivision (v) adds a definition of “non–sterile–to–sterile batch” for purposes of compounding drug products. The definition clarifies and specifies “non–sterile–to–sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non–sterile, regardless of intervening sterilization of that ingredient.
- Subdivision (w) adds a definition of “parenteral” for purposes of compounding drug products. The definition clarifies and specifies “parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.
- Subdivision (x) 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 (y) is renumbered from previous subdivision (c). Subdivision (y) amends the definition of “potency” for the purposes of compounding drug products. The definition clarifies and specifies “potency” means active ingredient strength within  $\pm 10\%$  (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 (z) 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 be sterile.
- Subdivision (aa) 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. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co–owned by, the prescriber’s practice environment.
- Subdivision (ab) 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 or better environment through the use of unidirectional HEPA–filtered first air for the exposure of critical sites when compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.
- Subdivision (ac) 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 repeated 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 (ad) 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 (ae) is renumbered from previous subdivision (d). Subdivision (ae) 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, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those noted on the master formula by adding “and the absence of inactive ingredients other than those noted on the master formula” to the definition. Additionally, the “and” before “absence of active” was removed for grammatical clarity.
- Subdivision (af) adds a definition of “segregated sterile compounding area” for purposes of compounding drug products. The definition clarifies and specifies “segregated compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile 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. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing non-hazardous sterile-to-sterile compounded preparations.
- Subdivision (ag) is renumbered from previous subdivision (e). Subdivision (ag) 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 is necessary in 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 “that may be 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 by the prescriber or the prescriber’s agent and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation, 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’s office and signed for by the prescriber or the prescriber’s agent; 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 for human medical practices, or a 120–hour supply for veterinary medical practices, solely to the prescriber’s own patients seen as part of regular treatment in the prescriber’s office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and.”
- Subdivision (c)(4) is renumbered from subdivision (c)(2) and further clarifies subdivision (c) by adding “That the pharmacist has a credible basis for concluding.”
- Subdivision (c)(5) is renumbered from subdivision (c)(3) and further clarifies subdivision (c) by 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. Additionally, “for” was deleted and replaced with “With regard to.” Finally, “to whom the pharmacy furnishes” and “with regard to” were added and “taken as a whole” was deleted for further clarity.
- 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 an 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 commercially available 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, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.
- Subdivision (e) is renumbered from previous subdivision (d) 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 maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.”
- 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 of a master formula.
- Subdivision (e)(8) further clarifies subdivision (e) by adding “Instructions for storage and handling of the compounded drug preparation.” This language was moved from section 1735.3 of the California Code of Regulations and added here as it should be maintain with the written master formula.
- Subdivision (f) is renumbered from previous subdivision (e) and replaces “product” with “preparation” in two places 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) is renumbered from previous subdivision (f) 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. Additionally, “the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation” was added to hold the pharmacist responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation if the storage and handling instructions are followed.

- Subdivision (h) is renumbered from previous subdivision (g) and deletes the “1” in the word “compendial” making word “compendia” for accuracy.
- Subdivision (i) is renumbered from previous subdivision (h) 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. “180 days from preparation” was relocated in the paragraph to read and amended to read “nor shall it exceed 1800 days from preparation” and “longer” was replaced with “later.” Finally, “the same” was changed to “identical” to clarify that identical components must be used.
- Subdivision (j) is renumbered from previous subdivision (i) 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.
- Previous subdivision (j) was removed from the regulation. The Pharmacy Compounding Self-Assessment must be re-designed to incorporate the changes with this regulation; as such, the self-assessment cannot be required as it will not be available.
- Subdivision (k) adds the following language to specify requirements for ingredients that are received without a supplier’s expiration date, “Packages of ingredients, both active and inactive, 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 and 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 and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions.”

- 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 Procedures 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).” Additionally, “If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply” was added to clarify the requirement for missing manufacturer expiration dates.
- 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. Additionally, “expressed in the compounding record in a standard date and time format” was added to specify how the information should be documented to maintain a universal format.

- 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 compounded.
- Subdivision (c) is reorganized to add “Active pharmaceutical ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other” and the “C” was changed from a capital to lowercase for grammar purposes. 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 phrases “, 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 and “either written in English or translated into English,” requiring certificate of purity or analysis be in English. The word “and” is added to include certificate of purity for chemicals, bulk drug substances, and drug products used in compounding. The words “, and components” are deleted for redundancy. “Food and Drug Administration” was changed to “FDA” is the second to last sentence. Finally, the sentence “Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding 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 are 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. Additionally, “or brand” was added to allow for both generic and brand names to be listed on the label.
- Subdivision (b) removes “or on the receipt” for a compounding statement and adds “Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to patient of the facility. To be treated as such, the “health care facility” must be licensed under Health and Safety Code section 1250.” to exempt health care facilities from the labeling requirement.
- 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 words “concentration or” was removed to restrict the label to strength, volume, or weight and “of the preparation” was added for clarity.

The necessity of these changes in 16 CCR §1735.4 are 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:

Through-out this section “policy and procedure” was amended to “policies and procedures” are there may be more than one at a given location.

- Subdivision (a) adds the sentence “Any failure to follow the pharmacy’s written policies and procedures shall constitute a basis 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. Additionally, “The policies and procedures manual” was added to the second sentence and “processes” was replaced with “policies and procedures” for clarification.
- Subdivision (c) adds a colon to the end of the text in the subdivision and “at least” is added to allow for the policies and procedures to contain additional information.
- Subdivision (c)(1) changes “processes or to the policy and procedure manual” to “policies and procedures.”
- Subdivision (c)(2) removed “Documentation of a” and replaces it with “A written.” 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. Additionally, “verification” was changed to “information” and “of a compounded drug product” was removed from the language as it was redundant. Finally, “The plan shall ensure that all affected doses can be accounted for during the recall” was added to ensure that a plan is established so recalled preparations are accounted for.
- Subdivision (c)(4) 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)(5) is renumbered from previous subdivision (4) and adds the phrase “The methodology must be appropriate to compounded 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)(6) is renumbered from previous subdivision (5) 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. Additionally, “and rationale or reference source” was added to clarify was documentation needs to be maintained.
- Subdivisions (c)(7), (8), (9) and (10) were added to further clarify requirements for compounding policies and procedures.
  - (7) Dates and signatures of annual reviews of the policies and procedures manual by the pharmacist-in-charge.
  - (8) Dates and signatures of any revisions to the policies and procedures manual approved by the pharmacist-in-charge.
  - (9) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
  - (10) 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 within the pharmacy.
- Business and Professions Code section 4301 is added to the References Cited to ensure compliance with the Administrative Procedures

Act. The word “and” is deleted and replaced later in the citation for accuracy.

The necessity of these changes in 16 CCR §1735.5 are 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. Additionally, “This shall include records of maintenance and cleaning of the facilities and equipment.” was added to ensure maintenance records are maintained and “also” was added to the third sentence for grammatical clarity.
- 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. Additionally, “and” was moved to after “maintained” and “cleaned” was added to ensure that equipment is cleaned according to the manufacturers’ specifications.
- 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 “, on a schedule and by a method determined by the manufacturer’s specifications,” is added to require pharmacy personnel to ensure the manufacturer’s specifications are included. Finally, “in writing” was replaced with “in a form which is not alterable” to allow for electronic records.
- Subdivision (d) was added and reads “Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.”

This information was moved from 1751.3 of the California Code of Regulations.

The necessity of these changes in 16 CCR §1735.6 are 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 (a) adds “Additionally, documentation demonstrating that staff have been trained on all policies and procedures shall be maintained” and moves this requirement from the policies and procedures to this section and this information should not be maintained in the policies and procedures.
- 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 are 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. Additionally, “analysis of compounded drug preparations to ensure” and “including the frequency of testing” was added to ensure these standards are documented in the quality assurance plan. The word “analysis” was removed for redundancy and “collated” was changed to “maintained along” for clarity. Finally, “The

quality assurance plan shall include a schedule for routine testing and analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis” was added to ensure that annual testing and analysis are defined in the quality assurance plan.

- 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 within the pharmacy or within patient care areas of a hospital where furnished drug is returned for re-dispensing.” to ensure policies and procedures address out-of-range temperature variations at locations where drugs may be held.

The necessity of these changes in 16 CCR §1735.8 are 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 or cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 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 505.5 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), (2), and (3) were deleted and as the language was combined to subdivision (b).
- Subdivision (b)(1) is renumbered from the previous subdivision (b)(4) to state, “Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.” This ensured the requirements for certification of ISO environments are done at least every six months in accordance with Section 1751.4 of the California

Code of Regulations. The words “for at least 3 years” were removed and replaced with “in the pharmacy”

- Subdivision (b)(2) is renumbered from previous subdivision (5). 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) is renumbered from previous subdivision (6). The additions of “.4” and “Chapter 12” were made to the first sentence to clarify the chapter and section numbers being referenced. The following sentence was added to specify the location of sinks and drains, “Sinks and drains shall not be present in any ISO Class 7 or better buffer area or cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 PEC. A sink may be located in an ante-area.”
- Subdivision (b)(4) is renumbered from previous subdivision (7). 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, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage” was added to the last sentence. These changes clarified the refrigerator/freezer requirements and the need for a power outage backup plan.
- Subdivision (c) is deleted in its entirety as it is redundant to have a regulation that requires compliance with a statute.
- 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. Additionally, section “4127.7” was removed from the References Cited and the reference was removed from the language and the word “and” was relocated for grammar.

The necessity of these changes in 16 CCR §1751 are 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 (a) is renumbered from previous subdivision (b) with the deletion of reference to the former subdivision (a) by deleting the following phrase “and subdivision (a).” The phrases “any pharmacy engaged in any compounding” and “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. Finally, “must be made and kept by” was relocated and changed to “shall make and keep” and “within” was added to ensure that the records are made and kept within the pharmacy for inspector review.

- Subdivision (a)(1) added “Documents evidencing” and deleted “product” and replaced it with “drug preparation policies 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 and ensure training documents are maintained. Additionally, an “s” was added to “evaluation” for grammar.
- Subdivision (a)(2) is added to include results of gloved fingertip testing assessments, “Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.”
- Subdivision (a)(3) is 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 tests.”
- Subdivision (a)(4) is added to include viable volumetric air and surface sampling, “Results of viable volumetric air and surface sampling.”
- Subdivision (a)(5) is renumbered from previous subdivision (a)(2) to include additional documentation of refrigerator and freezer temperature requirements. “Documents indicating daily recordation 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) is renumbered from previous subdivision (a)(3) and added an “(s)” to “certification” and “environment” to include all certifications for the sterile compounding environments.
- Subdivision (a)(7) is added to include requirements for air pressure differentials and air velocity documentation, “Documents indicating daily recordation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with

an immediate entry or opening to ISO rooms or areas.”

- Subdivision (a)(8) is renumbered from previous subdivision (a)(4) and the term “logs” was deleted and replaced with “records” for clarity.
- Subdivision (a)(9) is renumbered from previous subdivision (a) (5) to add the requirement of “Logs or other documentation” of inspections. The “I” from “Inspection” was changed to “i” and an “s” was added to “inspection” for accuracy. Additionally, “pharmaceutical products or raw ingredients” was replaced with “chemicals, bulk drug substances, drug products, or other ingredients” to align the verbiage with other usage within the regulation.
- Subdivision (a)(10) is renumbered from previous subdivision (a)(6).
- Subdivision (b) is 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, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, and license number of the 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 are required to update the sterile compounding record-keeping 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 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:

- “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) changed the “T” in telephone to lowercase with the addition of “The” at the beginning of the sentence. The term “, except” was deleted and replaced with “The telephone number is not required on the label” for clarity. 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 a” to “within the.” Finally, the term “pharmacy” was deleted as it applies to all compounding within a hospital and not just the pharmacy.
- Subdivision (b) deleted “concentration” and replaced it with “strength, volume, or weight” and the term “each” was added before “ingredient” for clarity and the “s” was removed from “ingredient” for grammar. 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” twice and replaced it with “hazardous” in both locations.

The necessity of these changes in 16 CCR §1751.2 are 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. The term “policy and procedure” was modified to “policies and procedures” for grammar.
- 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 “compounded 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 a “e” to further clarify the proper use of equipment and supplies.
- Subdivision (a)(4) is added to include garbing requirements, “Hand Hygiene and Garbing.”
- Subdivision (a)(5) is added to include media–fill testing, “Media–fill testing procedure.”
- Subdivision (a)(8) is added to include beyond use dating and preparation stability, “Compounded sterile drug preparation stability and beyond use dating.”
- Subdivision (a)(9) is added to include final quality checks, “Visual inspection and other final quality checks of sterile drug preparations.”
- Subdivision (a)(10) is added to include automated compounding devices, “Use of automated compounding devices (if applicable).”
- Subdivision (a)(11) is added to include non–sterile–to–sterile drug preparations, “Preparing sterile compounded drug preparations from non–sterile components (if applicable).”

- Subdivision (a)(12) is renumbered from previous subdivision (a)(4). The phrase “Training of staff in the preparation of sterile injectable drug products” was modified to read “Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique” to further clarify what records need to be maintained for uniformity.
- Subdivision (a) (12) is 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) is added to include pressure and airflow monitoring, “Airflow considerations and pressure differential monitoring.”
- Subdivision (a)(14) is added to include cleaning and maintenance, “Cleaning and maintenance of ISO environments and segregated compounding areas.”
- Subdivision (a)(15) is added to include a sampling plan, “An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.”
- Subdivision (a)(16) is added to include compounding aseptic isolators and compounding aseptic containment isolators, “For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer’s recommended purge time.”
- Subdivision (a)(17) is added to include temperature monitoring, “Temperature monitoring in compounding and controlled storage areas.”
- Subdivision (a)(18) is added to include certification and maintenance, “Facility management including certification and maintenance of controlled environments and related equipment.”
- Subdivision (a)(19) is added to include action levels for testing and sampling, “Action levels for colony-forming units (CFUs) detected during viable surface testing, glove fingertip and volumetric air sampling.”
- Subdivision (a)(20) is renumbered from previous subdivision (b) and reworded to add “The determination and approval by a pharmacist of” to the beginning of the sentence and the phrases “must be determined in writing” and “and must be reviewed by a pharmacist” were removed for clarity.
- Subdivision (a)(21) is renumbered from previous subdivision (c) and removed “Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues.” and added “Procedures for handling, compounding and disposal of hazardous agents.”
- Subdivision (a)(22) is added to include the portion of previous subdivision (c) that was removed in new subdivision (a)(21). The new language reads “Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.”
- Subdivision (a)(23) is added to include the cleaning schedule, “Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.”
- Subdivision (b) is renumbered from previous subdivision (d)(3)(I) and amended to change “batch” to “lot” as “batch” was removed from the regulation. The subdivision now reads: “For lot compounding, the pharmacy shall maintain a written policies and procedures manual that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:”
- Subdivision (b)(1) is added to further define the lot compounding requirements, “Use of master formulas and compounding work sheets.”
- Subdivision (b)(2) is added to further define the lot compounding requirements, “Appropriate documentation.”
- Subdivision (b)(3) is added to further define the lot compounding requirements, “Appropriate sterility and potency testing.”
- Subdivision (c) is renumbered from previous subdivision (d) and was rewritten to read “For non-sterile-to-sterile batch compounding, the pharmacy shall maintain a written policies and procedures manual for compounding that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:”

- Subdivision (c)(1) is renumbered from previous subdivision (d)(3)(J) and was amended to add “methods” following “Sterilization.”
- Subdivision (c)(2) is renumbered from previous subdivision (d)(3)(K).
- Subdivision (d) is renumbered from previous subdivision (d)(1) and amended to add “manuals and materials” to further clarify the items that need to be available. The term “these” was deleted and replaced with “compounding” for clarity and the term “to” was added for grammar.
- Subdivision (e) is renumbered from previous subdivision (d)(2) and amended to delete the word “injectable products” 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. “This review must be documented by a signature and date” was added to require that the policies and procedures be signed and dated.
- Subdivision (d)(3)–(d)(3)(H) are removed in their entirety as they are defined in other locations or are redundant.

The necessity of these changes in 16 CCR §1751.3 are 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 “products(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 lot;
  - (3) After each spill; and
  - (4) When surface contamination is known or suspected.”

- Subdivision (e) is renumbered from previous subdivision (d). 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 daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.”
- Subdivision (f) 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 air quality. 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 *or cleanroom* 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 or 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) is renumbered from previous subdivision (e). The term “parenteral cytotoxic” was deleted and replaced with “sterile hazardous” to specify the agents required. Additionally, Section “505.12.1” was changed to “505.5.1” due to a change in 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 replaced with “every six months.” 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 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), polypropylene or low shedding gown that closes in the back, shoe covers, and two layers of gloves with the outermost glove tested to meet ASTM 6978–05. Where the documentation provided by

CACI manufacturer does not require garbing, only the two glove requirement shall apply.”

- 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 quarterly for all sterile-to-sterile compounding and monthly for all non-sterile-to-sterile compounding. Volumetric air sampling by impaction shall be done at least once every six months. 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.”

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) is renumbered from previous subdivision (b). 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) is renumbered from previous subdivision (a)(3) and added “Compounding personnel shall not wear” and the “H” was changed to “h.” Additionally, 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.
- Previous subdivision (a)(4) was deleted for redundancy.
- 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 or cleanroom. 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 ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.”
- Subdivision (c) was deleted as previous subdivisions (a) and (b) were amended and subdivision (c) no longer applies.
- 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 are 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 or greater 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 required.
- 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 are 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 medication” 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) is renumbered from previous subdivision (a)(3).
- Subdivision (a)(3) is renumbered from previous subdivision (a)(4). 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, “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” as this is captured in identifying the aseptic media–fill test. This sentence was added to provide qualifications for a successful media test, “The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. 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 manufacture’s recommendations into the qualifications for successful media testing. The words “employee’s” and “and documented” were added and “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. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or personnel

found to be deficient” was added to specify competency revalidation for sterile to sterile compounding and non-sterile to sterile compounding. The words “repaired or” were deleted to leave only “replaced.”

- Subdivision (c) was added to specify and clarify what procedures are included in the initial competency evaluation, “All sterile 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) is renumbered from previous subdivision (c). Subdivision (e) was amended and deleted “Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients” and replaced with “Non-sterile-to-sterile batch drug preparations” to provide clarity. Additionally, “per USP chapter 85 limits, before dispensing” to detail the acceptable levels of pyrogens. Finally, “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” was added to clarify the testing requirements.
- Subdivision (d) was deleted as it was redundant.

The necessity of these changes in 16 CCR §1751.7 are 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 conformity with and 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 does not exceed the expiration date or beyond use date provided by the manufacturer for any component in the preparation, and that, 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, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days at controlled freezer temperature, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area or cleanroom 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.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days at controlled freezer temperature, where the sterile compounded drug

preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area or cleanroom 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.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days at controlled freezer temperature, where the sterile compounded drug preparation is compounded solely with aseptic manipulations 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. For the purposes of this subdivision, “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) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile 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.

(e)(1) 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. A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO Class 7 buffer area or cleanroom, with an ante-area.

(2) 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 are 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 contain-

ers 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 storage circumstance.

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 are 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 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 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 are 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*
- *In 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 pharmacist 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 deter-

mined 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 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 itself have any effect on the (1) creation or elimination 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 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 Eco-

conomic 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. She also indicated that 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](http://www.pharmacy.ca.gov)).

CONTACT PERSON

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

Name: Lori Martinez  
 Address: 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone No.: (916) 574-7917  
 Fax No.: (916) 574-8618  
 E-Mail  
 Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Karen Halbo  
 Address: 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone No.: (916) 574-7948  
 Fax No.: (916) 574-8618  
 E-Mail  
 Address: Karen.Halbo@dca.ca.gov

Website Access. Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

**TITLE 16. BOARD OF PHARMACY**

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (“Board”) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on June 22, 2015.

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

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

Authority and Reference: Under the authority conferred by Business and Professions Code (“B&P”) sections 4005, 4052(a)(10) and 4052.9, in order to implement, interpret and make specific Business and Professions Code sections 4052(a)(10) and 4052.9, the Board is proposing to amend Article 5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”), as follows:

INFORMATIVE DIGEST/POLICY STATEMENT  
OVERVIEW

The Board proposes to adopt Section 1746.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out a standard protocol for pharmacists to furnish nicotine replacement products without a doctor’s prescription. This adoption is necessary to carry out the purpose of B&P section 4052.9. This proposed rulemaking would increase access to nicotine replacement products which help people quit smoking. By following the proposed protocol, pharmacists may furnish, where medically appropriate, nicotine replacement products to the public.

**Specific Benefits Anticipated:** Having pharmacists furnish nicotine replacement products and smoking cessation therapy will reduce the cost and increase the convenience of obtaining those products. Californians quitting smoking will lead to a trickle-down effect on public health and safety by reducing smoking-related illnesses and deaths.

**Consistency and Compatibility with Existing State Regulation:** During the collaborative process of drafting the protocol set out in this regulation, the Board has conducted a search of similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

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

FISCAL IMPACT

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

**Effect on Housing Costs:** NONE.

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

**Results of Economic Impact Assessment:** Pharmacists wishing to dispense nicotine replacement products

must take two (2) hours of continuing education (CE) on the training of smoking cessation therapy and nicotine replacement therapy. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the two (2) hours of CE on nicotine replacement products can be applied to meet the existing CE requirement. Thus, while this regulatory proposal affects pharmacies, it will not have a significant statewide adverse economic impact directly affecting business, or businesses’ ability to compete.

**Impact on Jobs/New Businesses:** The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or elimination of jobs, or on the creation of new businesses or the elimination of existing businesses nor on the expansion of businesses in the State of California.

**Benefits of the Regulations:** This regulatory proposal benefits the health and welfare of California residents because having pharmacists dispense nicotine replacement products without a doctor’s prescription will make obtaining such products easier and cheaper. Nicotine replacement products are used to help people stop smoking. When people stop smoking, there is a positive trickle-down effect on public health and safety due to the reduction of smoking-related diseases and deaths.

The Board has determined that this regulation has no impact on worker safety.

This regulatory proposal does not affect the state’s environment because it simply allows pharmacists to continue dispensing nicotine cessation products pursuant to the protocol without a doctor’s prescription. Pharmacists have been dispensing nicotine cessation products with a doctor’s prescription for as long as such products have been available, and the Board has not received any information about measureable environmental effects.

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

**Business Report:** The proposed regulations do not require a new report to be made. Pharmacists have long been able to furnish nicotine cessation products to people who have a doctor’s prescription. While there might be a slight increase in demand for nicotine cessation products once individuals can obtain these products without a doctor’s prescription, the Board has concluded that this regulation will have a negligible effect on small businesses.

**Effect on Small Businesses:** The Board must determine that the proposed regulation would not affect small businesses. Pharmacists have long been able to furnish nicotine cessation products to individuals who have a doctor’s prescription. While there might be a slight increase in demand for nicotine cessation prod-

ucts once individuals can obtain without a doctor’s prescription, the Board has concluded that making this regulation permanent will have a negligible effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board’s attention, would either be more effective in carrying out the purpose for which the 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 policies or other provision of law.

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

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation and of the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the person designated below as Contact Person, or by accessing the Board of Pharmacy’s Web site at <http://www.pharmacy.ca.gov>.

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

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the contact 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 at <http://www.pharmacy.ca.gov>.

CONTACT PERSON

Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Inquiries or comments con-

cerning the proposed rulemaking actions may be addressed to:

Board of Pharmacy  
 Attn: Karen Halbo  
 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone: 916-574-7948  
 Fax No.: 916-574-8616  
 E-Mail: [Karen.Halbo@DCA.ca.gov](mailto:Karen.Halbo@DCA.ca.gov)

(Backup contact person)

Board of Pharmacy  
 Attn: Lori Martinez  
 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone: 916-574-7917  
 Fax No.: 916-574-8616  
 E-Mail: [Lori.Martinez@DCA.ca.gov](mailto:Lori.Martinez@DCA.ca.gov)

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (“Board”) proposes 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 p.m. on June 22, 2015.

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

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

Authority and Reference: Under the authority conferred by Business and Professions Code (“B&P”) sections 4005, 4052(a)(10) and 4052.3, in order to implement, interpret and make specific Business and Professions Code section 4052(a)(10) and § 4052.3, the Board is proposing to add to Article 5 of Division 17 of Title 16 of the California Code of Regulations, as follows:

INFORMATIVE DIGEST/ POLICY STATEMENT  
OVERVIEW

The Board proposes to adopt Section 1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out a protocol pharmacists will follow to furnish self-administered hormonal contraception (“contraception”) without a doctor’s prescription. Under existing law, women were required to obtain a prescription from a doctor to obtain self-administered hormonal contraception. In 2014, the American Congress of Obstetricians and Gynecologists issued a statement supporting “making oral contraceptives available over-the-counter,” to “help more women get the contraceptives they need.” This proposed rulemaking would allow women to obtain self-administered hormonal contraception from a pharmacist where medically appropriate, as determined by the pharmacist following the protocol.

The practice of pharmacy is authorized, regulated and enforced in California by the Board. Because the federal government does not authorize or regulate practice in California, there are no existing federal regulations comparable to this rulemaking.

**Specific Benefits Anticipated:** Increasing women’s access to highly effective self-administered hormonal contraception is likely to contribute to public health and safety by reducing unwanted pregnancies.

**Consistency and Compatibility with Existing State Regulation:** During the collaborative process of drafting the protocol set out in this regulation, the Board has conducted a search of similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. B&P section 4052.3 (the statute this regulation is clarifying) also authorizes pharmacists to dispense emergency contraception drug therapy pursuant to a protocol set out in 16 CCR Section 1746, and that regulation is not inconsistent with the proposed rulemaking.

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

FISCAL IMPACT:

- A. Cost or Savings to any state agency: NONE.
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE.
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE.

D. Other nondiscretionary cost or savings imposed on local agencies: NONE.

E. Cost or savings in federal funds to the state: NONE.

**Effect on Housing Costs:** NONE.

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

**Results of Economic Impact Assessment:** Pharmacists wishing to dispense self-administered hormonal contraception must take one (1) hour of continuing education (CE) on self-administered hormonal contraception, application of the USMEC for Contraceptive Use and other CDC guidance on contraception. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the one (1) hour of CE on self-administered hormonal contraception can be applied to meet the existing CE requirement. Thus, while this regulatory proposal affects pharmacies, it will not have a significant statewide adverse economic impact directly affecting business, or businesses’ ability to compete.

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

**Benefits of the Regulations:** This regulatory proposal benefits the health and welfare of California residents because having pharmacists dispense self-administered hormonal contraception will increase the availability of this highly effective form of contraception. Increasing women’s access to effective contraception will contribute to public health and safety by preventing unplanned pregnancies.

The Board has determined that this regulation has no impact on worker safety.

This regulatory proposal does not affect the state’s environment because it simply allows pharmacists to continue dispensing self-administered hormonal contraceptives, only now, when done pursuant to the protocol, the pharmacist may do so without a doctor’s prescription. Pharmacists have been dispensing self-administered hormonal contraception to women with doctor’s prescriptions for years, and the Board has not received any information about measureable environmental effects.

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

**Business Report:** The proposed regulations do not require a new report to be made. Pharmacists have been dispensing self-administered hormonal contraception to women for years, and maintain those patient medication records for three (3) years. That standard record-keeping requirement remains unchanged, as the proposed regulation simply allows pharmacists to dispense self-administered hormonal contraception pursuant to the protocol without a doctor's prescription.

**Effect on Small Businesses:** The Board has determined that the proposed regulation would not affect small businesses. Pharmacists have long been able to furnish contraceptives to women who have a doctor's prescription. While there might be a slight increase in demand for self-administered hormonal contraception once women can obtain it without a doctor's prescription, the Board has concluded that this regulation will have a negligible effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the 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 policies or other provisions of law.

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

INITIAL STATEMENT OF REASONS AND INFORMATION

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

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the person designated below as contact person, or by accessing the Board of Pharmacy's Web site at <http://www.pharmacy.ca.gov>.

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

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the contact 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 at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

CONTACT PERSON

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

Board of Pharmacy  
 Attn: Karen Halbo  
 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone: 916-574-7948  
 Fax No.: 916-574-8616  
 E-Mail: [Karen.Halbo@DCA.ca.gov](mailto:Karen.Halbo@DCA.ca.gov)

The backup contact person is:

Board of Pharmacy  
 Attn: Lori Martinez  
 1625 N. Market Blvd., N219  
 Sacramento, CA 95834  
 Telephone 916-574-7917  
 Fax No.: 916-574-8616  
 E-Mail: [Lori.Martinez@DCA.ca.gov](mailto:Lori.Martinez@DCA.ca.gov)

**GENERAL PUBLIC INTEREST**

**DEPARTMENT OF FISH AND WILDLIFE**

**PROPOSED RESEARCH AND RECOVERY ACTIONS FOR A FULLY PROTECTED SPECIES**

**Research and Recovery Actions for Santa Cruz Long-toed Salamanders (*Ambystoma macrodactylum croceum*) in Santa Cruz and Monterey Counties**

The Department of Fish and Wildlife (Department) received a proposal on April 27, 2015, from Kelli Ca-

mara, Program Director for the Resource Conservation District of Santa Cruz County (RCDSCC), requesting authorization to take the Santa Cruz Long-toed Salamander (*Ambystoma macrodactylum croceum*; "SCLTS"), for scientific research and recovery purposes associated with habitat creation, enhancement, and maintenance throughout the range of the species in Santa Cruz and Monterey counties, consistent with protection and recovery of the species. The SCLTS is a Fully Protected amphibian and is also listed as Endangered under the California Endangered Species Act and Endangered under the federal Endangered Species Act.

In coordination with the U.S. Fish and Wildlife Service (Service) and the Department, Ms. Camara is planning to manage and conduct habitat creation, enhancement, and maintenance actions along with population monitoring studies. Proposed activities will be drawn from existing conservation documents including: the Draft Revised Recovery Plan for SCLTS (Service 1999), SCLTS 5-Year Review (Service 2009), Strategic Plan for Recovery of the SCLTS and California red-legged frog ("CRLF") (RCDSCC 2013), SCLTS Conceptual Area Protection Plan (Department 2010), and the Moro Cojo Slough Management and Enhancement Plan (The Habitat Restoration Group 1996). Other past or future plans that contain Service- and Department-recommended activities to assist in the recovery of SCLTS may also be utilized to design and implement additional projects. California tiger salamanders ("CTS") and CRLF co-occur with SCLTS at some sites and are expected to also benefit from the proposed actions. Pre-construction surveys and avoidance and minimization measures have been developed to reduce the likelihood of injury or mortality of SCLTS, CTS, and CRLF associated with habitat improvement and maintenance work.

The goal of the proposed actions is to contribute to the recovery of SCLTS. The following objectives have been identified as being essential elements to achieve the stated recovery goal:

- (1) Manage pond and upland habitats by ensuring that existing ponds remain, or become, functional breeding sites and by securing and managing upland habitats to provide hydrologic integrity to the ponds and adequate cover and food for non-breeding SCLTS.
- (2) Establish additional ponds and/or restore existing ponds.
- (3) Reduce human-related mortality by evaluating roadkills and installing fencing or tunnels.
- (4) Survey for and identify habitat for protection.
- (5) Determine and monitor population status.

The Department intends to issue, under specified conditions, a Memorandum of Understanding (MOU)

to authorize qualified professional wildlife researchers, with Kelli Camara as the Principal Investigator, to carry out the proposed research and recovery activities. The applicant is also required to have, and is in the process of obtaining, a valid federal recovery permit for the SCLTS, CTS, and CRLF.

Pursuant to California Fish and Game Code (FGC) Section 5050(a)(1), the Department may authorize take of Fully Protected amphibians after 30 days' notice has been provided to affected and interested parties through publication of this notice. If the Department determines that the proposed research and recovery activities are consistent with the requirements of FGC Section 5050 for take of Fully Protected amphibians, it will issue the MOU on or after June 8, 2015, expiring in 2020. The MOU may be subsequently renewed. Contact: Laura Patterson, Wildlife Branch, [Laura.Patterson@wildlife.ca.gov](mailto:Laura.Patterson@wildlife.ca.gov), 916-341-6981.

**DECISION NOT TO PROCEED**

**BOARD OF PHARMACY**

**Re: Notice of Proposed Rulemaking concerning Compounding Drug Preparations**

Pursuant to Government Code Section 11347, the California Board of Pharmacy (board) hereby gives notice that it has decided not to proceed with the rulemaking action published in the California Regulatory Notice Register on September 5, 2014, Register 2014, No. 36-Z. The proposed rulemaking concerned Compounding Drug Preparations. (OAL Notice Z2014-0826-05.)

Any interested person with questions concerning this rulemaking should contact Lori Martinez at either 916-574-7917 or by e-mail at: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov).

The board will also post this Notice of Decision Not to Proceed on its website.

**BOARD FOR PROFESSIONAL ENGINEERS, LAND SURVEYORS, AND GEOLOGISTS**

**NOTICE OF DECISION NOT TO PROCEED WITH RULEMAKING ACTION**

The Board for Professional Engineers, Land Surveyors and Geologists (Board) has decided not to proceed with its rulemaking action described in the Notice pub-

lished in the California Regulatory Notice Register on May 23, 2014 (Register 2014, No. Z-2014-0513-08), regarding the Substantial Relationship Criteria regulations (Title 16, California Code of Regulations Sections 416 and 3060).

**RULEMAKING PETITION  
DECISION**

**DEPARTMENT OF FOOD AND  
AGRICULTURE**

**Decision on Petition**

**Subject:** Petition to Establish an Emergency Interior Quarantine for the Polyphagus Shot Hole Borer (PSHB)

**Decision:** Deny

**Petition:** Any interested party has a right to obtain a copy of the petition to the agency by contacting the agency contact person listed below.

**Agency:** California Department of Food and Agriculture (CDFA)

**Party Submitting Petition:** John Snyder, Riverside County Agricultural Commissioner/Sealer of Weights and Measures

**California Code of Regulations:** Interior quarantines are established in Title 3, with a section number of 34XX.

**California Food and Agricultural Code (FAC):** Existing law provides that the Secretary may establish, maintain and enforce quarantine, eradication and other such regulations as necessary to protect the agricultural industry from the introduction and spread of pests (FAC sections 407, 5301, 5302, and 5322)

**Reasons Supporting the Denial:** The appearance of PSHB in Southern California has created a complex issue. PSHB was first detected in the state in 2003 in Whittier Narrows and it was believed at that time to have a limited number of hosts. By 2014 it now has been found to attack over 200 species of trees. Additionally, it is now established in Los Angeles, Orange, Riverside and San Diego counties.

PSHB is also established in Israel where it spreads at a rate of about 12 miles per year naturally. In Israel, just as in California, there is no good insecticidal or biocontrol strategies which have been successful. There are no commercially available sex or aggregation pheromones which serve as attractants for detection.

The sole purpose of a quarantine is to prevent the artificial spread of the targeted pest. To minimize natural

spread from the quarantine area there is generally an eradication or suppression or control component. Based upon the known biology of PSHB, quarantine restrictions will not be an effective method to mitigate the artificial spread of the PSHB for the following reasons:

1. No comprehensive official statewide PSHB survey has been completed;
2. The complete host range for PSHB is still unknown;
3. The ability to accurately delimit the extent of the infested area using the detection technology currently available is unlikely to achieve that goal in a cost effective manner;
4. A quarantine would have to apply to all host material including woody ornamental nursery stock, fire wood, and green waste in order to ensure that all potential pathways for artificial spread were addressed. Quarantine restrictions against firewood are generally not cost effective and do not prevent artificial spread because it is frequently moved by homeowners, and;
5. A quarantine is unlikely to effectively prevent the movement of host material inside the regulated area. Since the PSHB can spread long distances on its own the infested area will continue to naturally expand thus nullifying any perceived long term benefit to areas of Riverside County currently not known to be infested.

**Agency Contact Person:**

Stephen Brown, Assistant Director  
CDFA  
Plant Health and Pest Prevention Services  
1220 N Street  
Sacramento, CA 95814  
Phone: (916) 654-0317  
Fax: (916) 651-2900

**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# 2015-0313-01

BOARD OF FORESTRY AND FIRE PROTECTION  
SRA Fire Safe Regulations Update, 2014

In this resubmitted regulatory action, the Board is amending sections in Title 14 of the California Code of Regulations to set standards for future design and construction of structures, subdivisions and developments in State Responsibility Area (SRA) and provide for basic emergency access and perimeter wildfire protection.

Title 14  
California Code of Regulations  
AMEND: 1273.01, 1273.02, 1273.05, 1273.06, 1273.07, 1273.08, 1273.10, 1273.11, 1274.01, 1274.09, 1275.00, 1275.01, 1275.10, 1275.15, 1276.00, 1276.03  
Filed 04/27/2015  
Effective 01/01/2016  
Agency Contact: Thembi Borrás (916) 653-9633

File# 2015-0316-01  
BUREAU OF REAL ESTATE APPRAISERS  
Citizenship or Immigrant Status of Applicants

This change without regulatory effect by the Bureau of Real Estate Appraisers (“BRE”) repeals section 3530 in title 10 of the California Code of Regulations (“CCR”). Business and Professions Code section 135.5 (added by Stats.2014, c. 752 (S.B.1159), § 2, eff. Jan. 1, 2015), subdivision (b) states, in relevant part, that “no entity within the [Department of Consumer Affairs] shall deny licensure to an applicant based on his or her citizenship status or immigration status.” Currently, Section 3530 allows BRE to deny licensure to applicants based on their citizenship or immigration status. BRE is repealing Section 3530 pursuant to subdivision (a)(6) of section 100 of the CCR to prevent denial of licensure based on citizenship or immigration status.

Title 10  
California Code of Regulations  
REPEAL: 3530  
Filed 04/27/2015  
Agency Contact: Kyle Muteff (916) 341-6126

File# 2015-0417-02  
CALIFORNIA HEALTH BENEFIT EXCHANGE  
Medi-Cal Managed Care Plan Enrollment Assistance

This emergency rulemaking action establishes the process for Medi-Cal Managed Care Plans (MMCPs) to become Certified MMCPs to provide enrollment assistance to consumers, as well as the process for individuals, whether employees or contractors of MMCPs, to become certified to provide enrollment assistance to consumers. The action adopts new provisions concerning Certification application, eligibility, and training requirements, provisions listing roles and responsibilities of Certified MMCPs and Certified MMCP Enrollers,

conflict-of-interest rules, and grounds for suspension and revocation of Certification.

Title 10  
California Code of Regulations  
ADOPT: 6900, 6901, 6902, 6903, 6904, 6905, 6906, 6907, 6908  
Filed 04/27/2015  
Effective 04/27/2015  
Agency Contact: Tessa Hammer (916) 228-8232

File# 2015-0417-01  
CALIFORNIA SCHOOL FINANCE AUTHORITY  
Charter School Facility Grant Program

This emergency rulemaking action by the California School Finance Authority (Authority) implements regulations to govern administration of the Charter School Facility Grant Program, under which the Authority administers approximately \$92,000,000 in general fund assistance to charter schools for facilities rent and lease costs.

Title 4  
California Code of Regulations  
AMEND: 10170.2, 10170.3, 10170.4, 10170.5, 10170.6, 10170.7, 10170.8, 10170.9, 10170.10, 10170.11  
Filed 04/27/2015  
Effective 04/27/2015  
Agency Contact: Katrina Johantgen (213) 620-2305

File# 2015-0318-02  
DEPARTMENT OF CORRECTIONS AND REHABILITATION  
Case Management Reentry Pilot Program

This File/Print submission establishes the Case Management Reentry Pilot Program as mandated by Penal Code section 3016. The program is for certain offenders under the jurisdiction of the Department who are likely to benefit from a case management reentry strategy. Pursuant to Penal Code sections 3016 and 5058.1, the program will remain in effect for three years.

Title 15  
California Code of Regulations  
ADOPT: 3999.18  
Filed 04/27/2015  
Effective 04/27/2015  
Agency Contact: Josh Jugum (916) 445-2228

File# 2015-0312-02  
DEPARTMENT OF CORRECTIONS AND REHABILITATION  
Non-Substantive Changes — Civil Addicts

These changes without regulatory effect by the Department of Corrections and Rehabilitation (the “Department”) amend six sections in title 15 of the Califor-

nia Code of Regulations (the “CCR”). Senate Bill 1021 (2011–2012 Reg. Sess.) eliminated the Civil Addict Program (the “Program”) encompassed in Chapter 1 (commencing with Section 3000) of Division 3 of the Welfare and Institutions Code. These changes without regulatory effect delete references to and regulatory provisions regarding the Program in division 3 of title 15 of the CCR.

Title 15  
California Code of Regulations  
AMEND: 3001, 3042, 3043, 3084.7, 3379, 3768.2  
Filed 04/22/2015  
Agency Contact: Laura Lomonaco (916) 445–2217

File# 2015–0310–02  
DEPARTMENT OF WATER RESOURCES  
Encroachment Permit Program for Department of Water Resources

In this resubmitted regulatory action, the Department is adding Chapter 6, entitled “Encroachments,” to Title 23 of the California Code of Regulations. The regulations set forth the requirements for obtaining an Encroachment Permit. The regulations also outline the Department’s review process, associated costs to the applicant, and implement the enforcement provisions of Water Code section 12899, in order to allow the Department to limit unauthorized encroachments and control access to the right-of-way.

Title 23  
California Code of Regulations  
ADOPT: 600, 600.1, 600.2, 600.3, 600.4, 601, 602, 603, 603.5, 604, 605, 606, 607.1, 607.2, 607.3, 608.1, 608.2, 608.3, 610.1, 610.2, 610.3, 610.4, 610.5, 610.6, 610.7, 610.8, 610.9, 610.10, 610.11, 612.1, 612.2, 612.3, 612.4, 612.5, 612.6, 612.61, 612.62, 612.63, 612.64, 612.65, 612.66, 612.67, 615.1, 615.2, 615.3, 618, 620, 625.1, 625.2, 625.3, 625.4, 625.5, 625.6, 625.7, 635.0  
Filed 04/22/2015  
Effective 07/01/2015  
Agency Contact:  
Leroy Ellinghouse (916) 653–7168

File# 2015–0410–01  
FAIR POLITICAL PRACTICES COMMISSION  
Conflict of Interest Reorganization (Nonsubstantive)

This action by the Fair Political Practices Commission (Commission) revises and renumbers numerous regulation sections pertaining to conflicts of interest.

OAL’s review of FPPC proposed regulations is limited to the provisions of the APA as it was enacted on June 4, 1974, when voters adopted the California Political Reform Act. (Fair Political Practices Commission

v. Office of Administrative Law, Linda Stockdale Brewer, (April 27, 1992, C010924 [nonpub. opn.]) OAL’s review is limited to determining if the proposed regulations comply with “the form and style prescribed by the Secretary of State. If the department approves the regulation or order of repeal for filing, it shall endorse on the certified copy thereof its approval for filing and shall transmit such copy to the Secretary of State.” (Former Gov. Code, sec. 11380.2, repealed by Stats. 1979, ch. 567, § 2.)

Title 2  
California Code of Regulations  
AMEND: 18700, 18700.1, 18700.2, 18700.3, 18701, 18701.1, 18702, 18702.1, 18702.2, 18702.3, 18702.4, 18702.5, 18703.3, 18704, 18704.1, 18704.2, 18704.3, 18704.4, 18704.5, 18704.6, 18705, 18705.1, 18705.2, 18705.3, 18705.4, 18705.5, 18706, 18706.1, 18708, 18709  
Filed 04/27/2015  
Effective 04/27/2015  
Agency Contact:  
Virginia Latteri–Lopez (916) 322–5660

File# 2015–0416–01  
FISH AND GAME COMMISSION  
Pacific Halibut Sport Fishing

This action by the Fish and Game Commission amends sections in Title 14, California Code of Regulations regarding the recreational Pacific halibut fishery. These amendments make state regulations for halibut season length and gear restrictions consistent with the federal sport fishing rules for the 2015 fishing season. The amendments set the season dates and implement a quota for the 2015 season.

Title 14  
California Code of Regulations  
AMEND: 28.20, 28.95  
Filed 04/28/2015  
Effective 04/28/2015  
Agency Contact: Sherrie Fonbuena (916) 654–9866

File# 2015–0417–03  
FISH AND GAME COMMISSION  
Sacramento River Closure Due to Drought Conditions

Through this emergency rulemaking, the Fish and Game Commission (the “Commission”) amends subdivision (b)(156.5)(B) of section 7.50 of title 14 of the California Code of Regulations. Specifically, the Commission is amending Section 7.50(b)(156.5)(B) to close all fishing in the Sacramento River from 650 feet below Keswick Dam to the Highway 44 bridge through July 31, 2015. The Commission is closing all fishing in this portion of the Sacramento River to protect the winter-run Chinook salmon.

Title 14  
 California Code of Regulations  
 AMEND: 7.50  
 Filed 04/24/2015  
 Effective 04/24/2015  
 Agency Contact: Sheri Tiemann (916) 654-9872

02/02/15 AMEND: 18450.11  
 02/02/15 AMEND: 18740  
 01/22/15 AMEND: 54300  
 12/31/14 ADOPT: 20620 AMEND: 20610, 20611, 20612, 20613, 20622 and renumber as 20621, 20623 and renumber as 20622, 20624 and renumber as 20623, 20625 and renumber as 20624, 20626 and renumber as 20625, 20627 and renumber as 20626, 20630, 20631, 20632, 20633, 20635 and renumber as 20634, 20636 and renumber as 20635, 20637 and renumber as 20636, 20638 and renumber as 20637, 20639 and renumber as 20638, 20640, 20641, 20642, 20645 and renumber as 20643, 20646 and renumber as 20644, 20650, 20651, 20652, 20653, 20654, 20660, 20661, 20662, 20663, 20670, 20672, 20680, 20681, 20682 REPEAL: 20620, 20621, 20671, Appendices A and B to Chapter 6

**CCR CHANGES FILED  
 WITH THE SECRETARY OF STATE  
 WITHIN November 26, 2014 TO  
 April 29, 2015**

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**

04/27/15 AMEND: 18700, 18700.1, 18700.2, 18700.3, 18701, 18701.1, 18702, 18702.1, 18702.2, 18702.3, 18702.4, 18702.5, 18703.3, 18704, 18704.1, 18704.2, 18704.3, 18704.4, 18704.5, 18704.6, 18705, 18705.1, 18705.2, 18705.3, 18705.4, 18705.5, 18706, 18706.1, 18708, 18709  
 04/09/15 AMEND: 57400  
 04/08/15 AMEND: 212  
 04/07/15 ADOPT: 59780  
 04/02/15 AMEND: 18215  
 04/02/15 AMEND: 18530.4, 18530.45  
 03/24/15 AMEND: 1900  
 03/23/15 AMEND: 1189.10  
 03/23/15 AMEND: 59740  
 03/17/15 AMEND: 549  
 03/04/15 AMEND: 11087, 11088, 11089, 11090, 11091, 11092, 11093, 11094, 11095, 11096, 11097 REPEAL: 11098  
 02/23/15 ADOPT: 59760  
 02/23/15 ADOPT: 553, 553.1, 553.2, 553.3, 553.4, 553.5, 553.6, 599.100, 599.101, 599.102, 599.120, 599.121, 599.122, 599.123, 599.124, 599.140, 599.141, 599.142, 599.143, 599.144, 599.145, 599.146, 599.160, 599.161, 599.162, 599.163, 599.164  
 02/09/15 AMEND: 1859.76  
 02/02/15 AMEND: 18705, 18705.3, 18705.4, 18705.5 REPEAL: 18704, 18704.1, 18704.5

12/18/14 ADOPT: 1859.167.1, 1859.167.2, 1859.167.3 AMEND: 1859.2, 1859.77.4, 1859.106.1, 1859.160, 1859.161, 1859.162, 1859.163, 1859.163.1, 1859.163.4, 1859.163.5, 1859.164, 1859.164.1, 1859.164.2, 1859.165, 1859.166, 1859.166.1, 1859.167, 1859.167.2 (renumbered as 1859.167.4), 1859.167.3 (renumbered as 1859.167.5), 1859.168, 1859.171, 1859.172  
 12/16/14 ADOPT: 557  
 12/15/14 AMEND: 18545, 18703.4, 18730, 18940.2  
 12/15/14 AMEND: 18704.1, 18705.1  
 12/15/14 AMEND: 18704  
 12/10/14 ADOPT: 20700, 20701, 20702, 20703, 20704, 20705, 20706, 20707  
 12/03/14 AMEND: 51.7

**Title 3**

04/16/15 AMEND: 6512  
 04/15/15 ADOPT: 6738.1, 6738.2, 6738.3, 6738.4 AMEND: 6000, 6702, 6720, 6724, 6738, 6739, 6764, 6771, 6793, 6795 REPEAL: 6486.7, 6736  
 04/09/15 AMEND: 3435(b)  
 04/08/15 AMEND: 3435(b)  
 04/06/15 AMEND: 3  
 03/20/15 AMEND: 3435(b)  
 03/17/15 AMEND: 1428.6, 1428.7, 1428.8, 1428.10, 1428.12  
 03/02/15 AMEND: 3435(b)  
 02/25/15 AMEND: 2  
 02/18/15 AMEND: 4500

**CALIFORNIA REGULATORY NOTICE REGISTER 2015, VOLUME NO. 19-Z**

02/12/15 AMEND: 3435(b)  
 02/02/15 AMEND: 1392.8.1  
 01/27/15 AMEND: 3591.13(a)  
 01/26/15 AMEND: 3435(b)  
 01/21/15 AMEND: 300, 301  
 01/16/15 AMEND: 3435  
 01/02/15 AMEND: 3435(b)  
 12/23/14 AMEND: 1380.19, 1442.7  
 12/01/14 AMEND: 1310, 1310.1

**Title 4**

04/27/15 AMEND: 10170.2, 10170.3, 10170.4,  
 10170.5, 10170.6, 10170.7, 10170.8,  
 10170.9, 10170.10, 10170.11  
 04/21/15 AMEND: 150  
 04/09/15 AMEND: 10176, 10177, 10178, 10179,  
 10180, 10181, 10182, 10183, 10187  
 04/07/15 AMEND: 87102, 87455, 87465, 87469,  
 87615, 87616, 87632, 87633  
 04/06/15 ADOPT: 10080, 10081, 10082, 10083,  
 10084, 10085, 10086, 10087  
 04/06/15 AMEND: 278  
 03/30/15 ADOPT: 8078.3, 8078.4, 8078.5, 8078.6,  
 8078.7  
 03/13/15 AMEND: 5205, 5230  
 03/10/15 ADOPT: 10170.16, 10170.17, 10170.18,  
 10170.19, 10170.20, 10170.21,  
 10170.22, 10170.23, 10170.24  
 03/09/15 ADOPT: 10091.1, 10091.2, 10091.3,  
 10091.4, 10091.5, 10091.6, 10091.7,  
 10091.8, 10091.9, 10091.10, 10091.11,  
 10091.12, 10091.13, 10091.14, 10091.15  
 03/04/15 AMEND: 1866  
 03/02/15 AMEND: 1688  
 02/26/15 ADOPT: 24465-3  
 02/02/15 ADOPT: 12003, 12311, 12312, 12313,  
 12315, 12316 AMEND: 12002  
 REPEAL: 12400, 12401, 12402, 12403,  
 12404, 12405, 12406, 12410  
 01/30/15 AMEND: 10085  
 01/13/15 ADOPT: 5600, 5610, 5620, 5630, 5640  
 AMEND: 5000, 5144, 5170, 5200, 5205,  
 5230, 5240, 5255, 5350, 5370  
 01/13/15 AMEND: 1858  
 12/24/14 AMEND: 106(d)  
 12/15/14 AMEND: 10080, 10081, 10082, 10083,  
 10084, 10085, 10086  
 12/05/14 ADOPT: 10080, 10081, 10082, 10083,  
 10084, 10085, 10086, 10087

**Title 5**

03/12/15 AMEND: 19810  
 02/18/15 ADOPT: 58621 AMEND: 58601, 58612,  
 58620

01/30/15 ADOPT: 71105, 71105.5, 71410, 71471,  
 71775, 71775.5, 74240, 74250, 75140  
 AMEND: 70000, 71400, 71650, 75150  
 01/20/15 ADOPT: 80693, 80694  
 01/08/15 ADOPT: 15494, 15495, 15496, 15497,  
 15497.5  
 12/04/14 AMEND: 76120  
 12/04/14 AMEND: 30040, 30042.5  
 12/01/14 AMEND: 1514, 3380

**Title 8**

04/20/15 ADOPT: 9792.21.1, 9792.25.1 AMEND:  
 9792.20, 9792.21, 9792.23, 9792.24.1,  
 9792.24.3, 9792.25, 9792.26  
 04/06/15 AMEND: 9701, 9702  
 04/06/15 ADOPT: 17300, 17301, 17302, 17303,  
 17304, 17305, 17306, 17307, 17308,  
 17309, 17310  
 04/03/15 AMEND: 3395  
 02/25/15 AMEND: 9789.25  
 02/12/15 AMEND: 333, 336  
 02/04/15 AMEND: 9789.10, 9789.11, 9789.20,  
 9789.21, 9789.22, 9789.23, 9789.25,  
 9789.50, 9789.60, 9789.70, 9789.110,  
 9789.111, 9790  
 12/04/14 AMEND: 9789.39  
 12/02/14 AMEND: 5620, 6165, 6180, 6181, 6182,  
 6183, 6184  
 12/01/14 AMEND: 1514, 3380  
 11/26/14 AMEND: 5155

**Title 9**

03/09/15 AMEND: 4210

**Title 10**

04/27/15 REPEAL: 3530  
 04/27/15 ADOPT: 6900, 6901, 6902, 6903, 6904,  
 6905, 6906, 6907, 6908  
 04/13/15 ADOPT: 5508, 5509, 5510, 5511, 5512,  
 5513, 5514, 5515, 5516  
 03/25/15 AMEND: 2303, 2303.1, 2303.2, 2303.3,  
 2303.4, 2303.5, 2303.6, 2303.7, 2303.8,  
 2303.9, 2303.10, 2303.11, 2303.12,  
 2303.13, 2303.14, 2303.16, 2303.17,  
 2303.18, 2303.19, 2303.20, 2303.21,  
 2303.22, 2303.23, 2303.24, 2303.25  
 03/18/15 ADOPT: 6432  
 03/16/15 ADOPT: 6426, 6434  
 02/19/15 ADOPT: 6432  
 02/05/15 ADOPT: 8000, 8010, 8020, 8030, 8040  
 02/05/15 ADOPT: 6428, 6430  
 02/02/15 AMEND: 3528  
 01/30/15 ADOPT: 2240.15, 2240.16, 2240.6,  
 2240.7 AMEND: 2240, 2240.1, 2240.4,  
 2240.5

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- 01/20/15 AMEND: 2695.85
- 01/08/15 AMEND: 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2507.1, 2507.2, 2508, 2509
- 01/02/15 AMEND: 2698.95
- 12/12/14 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
- 12/12/14 ADOPT: 6657, 6658, 6660, 6664, 6670
- 12/10/14 AMEND: 2498.4.9
- 12/08/14 AMEND: 2498.6
- 12/04/14 AMEND: 2717
- Title 11**
- 03/09/15 ADOPT: 4250, 4251, 4252, 4253, 4254, 4255, 4256, 4257, 4258, 4259
- Title 13**
- 04/09/15 AMEND: 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629
- 01/23/15 AMEND: 553.70
- 01/21/15 AMEND: 1159
- 12/31/14 AMEND: 2025
- 12/17/14 ADOPT: 2416, 2417, 2418, 2419, 2419.1, 2419.2, 2419.3, 2419.4
- 12/17/14 ADOPT: 2416, 2417, 2418, 2419, 2419.1, 2419.2, 2419.3, 2419.4
- 12/01/14 ADOPT: 16.00, 16.02, 16.04, 16.06, 16.08, 16.10, 16.12, 16.14
- Title 13, 17**
- 01/23/15 AMEND: 553.70
- 01/21/15 AMEND: 1159
- 12/05/14 AMEND: Title 13: 1900, 1956.8, 2036, 2037, 2112, 2139, 2140, 2147, 2485; Title 17: 95300, 95301, 95302, 95303, 95305
- Title 14**
- 04/28/15 AMEND: 28.20, 28.95
- 04/27/15 AMEND: 1273.01, 1273.02, 1273.05, 1273.06, 1273.07, 1273.08, 1273.10, 1273.11, 1274.01, 1274.09, 1275.00, 1275.01, 1275.10, 1275.15, 1276.00, 1276.03
- 04/24/15 AMEND: 7.50
- 04/20/15 ADOPT: 1760.1, 1779.1
- 04/06/15 AMEND: 15411
- 04/01/15 AMEND: Heading of Division 7
- 04/01/15 AMEND: 1.73, 27.75, 27.80
- 03/30/15 ADOPT: 3550.17
- 03/10/15 AMEND: 1.91, 27.20, 27.25, 27.30, 27.35, 27.40, 27.45, 27.50, 27.51, 27.65, 28.26, 28.27, 28.28, 28.29, 28.48, 28.49, 28.54, 28.55, 58.56, 28.58, 28.90
- 02/23/15 AMEND: 1.45, 2.09, 4.05, 5.00, 5.80, 7.50, 8.00, 27.90
- 01/30/15 AMEND: 465, 472
- 01/29/15 AMEND: 1665.1, 1665.2, 1665.3, 1665.4, 1665.5, 1665.6, 1665.7, 1665.8
- 01/28/15 AMEND: 4351.1 (renumbered as 4351), 4360 REPEAL: 4351
- 12/30/14 ADOPT: 1751, 1761, 1777.4, 1780, 1781, 1782, 1783, 1783.1, 1783.2, 1783.3, 1784, 1784.1, 1784.2, 1785, 1785.1, 1786, 1787, 1788, 1789
- 12/29/14 AMEND: 1665.7
- 12/29/14 AMEND: 670.5
- 12/16/14 AMEND: 790, 791.6, 791.7, 795
- 12/10/14 AMEND: 895.1, 1038, 1039.1, 1041, 1092.01, 1092.28 REPEAL: 1038
- 11/26/14 AMEND: 923.2 [943.2, 963.2], 923.4 [943.4, 963.4], 923.5 [943.5, 963.5], 923.9 [943.9, 963.9]
- Title 15**
- 04/27/15 ADOPT: 3999.18
- 04/22/15 AMEND: 3001, 3042, 3043, 3084.7, 3379, 3768.2
- 04/16/15 ADOPT: 3410.1 AMEND: 3173.2
- 03/17/15 ADOPT: 3410.2 AMEND: 3000, 3173.2, 3287, 3410.1
- 03/16/15 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
- 03/12/15 REPEAL: 3999.13
- 02/11/15 REPEAL: 3999.11
- 02/09/15 ADOPT: 8121
- 01/28/15 ADOPT: 3364.1, 3364.2 AMEND: 3351, 3364
- 12/22/14 ADOPT: 3620, 3621, 3622, 3623, 3624, 3625, 3626 AMEND: 3000, 3521.1, 3521.2, 3545, 3800.2 REPEAL: 3620, 3625
- 12/04/14 AMEND: Renumber 8125 to 8199
- 12/03/14 AMEND: Renumber Section 8002 to 8901
- 12/01/14 AMEND: 4604, 4605
- 11/26/14 REPEAL: 2600, 2603, 2604, 2605, 2606, 2615, 2616, 2617, 2618, 2619, 2620, 2635, 2635.1, 2636, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2646.1, 2647, 2647.1, 2648, 2649, 2710, 2711, 2712, 2714
- Title 16**
- 04/10/15 ADOPT: 1746.3

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04/09/15	ADOPT: 1399.326, 1399.329, 1399.343, 1399.344, 1399.345, 1399.346 AMEND: 1399.301, 1399.350, 1399.351, 1399.352, 1399.395	30348.1, 30350 REPEAL: 30192, 30210.2, 30237
04/09/15	AMEND: 4161	12/10/14 AMEND: 94014, 94016
04/08/15	AMEND: 3306, 3310, 3340.10, 3351.1	12/05/14 ADOPT: 95660, 95661, 95662, 95663, 95664
04/01/15	ADOPT: 914.1, 914.2 AMEND: 918, 921, 921.1, 921.2	<b>Title 18</b>
03/26/15	ADOPT: 977, 980.4 AMEND: 978, 979, 980, 980.1, 980.2, 980.3, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994	03/19/15 AMEND: 472, 902, 904
03/26/15	AMEND: 3373	03/04/15 AMEND: 6001
03/25/15	ADOPT: 1361.5, 1361.51, 1361.52, 1361.53, 1361.54, 1361.55 AMEND: 1361	02/09/15 AMEND: 1588
03/18/15	AMEND: 2649	01/28/15 AMEND: 140.1
03/06/15	REPEAL: 950.8, 950.9	12/09/14 AMEND: 18662-0, 18662-3, 18662-4, 18662-5, 18662-6, 18662-8
01/21/15	AMEND: 1387	<b>Title 20</b>
01/12/15	AMEND: 601.3, 601.5, 620, 621, 622, 628, 631, 631.1	03/12/15 AMEND: 3103
01/08/15	AMEND: 1707.5	03/04/15 AMEND: 1682(c)
12/30/14	ADOPT: 832.22, 833	<b>Title 21</b>
12/23/14	AMEND: 116	02/12/15 ADOPT: 1469, 1470, 1471
12/22/14	AMEND: 1948	<b>Title 22</b>
12/17/14	AMEND: 109	04/07/15 AMEND: 51516.1
12/17/14	AMEND: 1399.541	02/09/15 AMEND: 97177.15, 97244
12/03/14	AMEND: 2610	02/05/15 ADOPT: 100018, 100020, 100025, 100026, 100027, 100028, 100029, 100030 AMEND: 100005, 100007, 100009, 100014, 100015, 100016, 100017, 100018, 100020, 100021, 100025, 100026, 100027 REPEAL: 100013, 100019, 100022, 100023, 100024, 100028
<b>Title 17</b>		12/31/14 AMEND: 97174
02/27/15	AMEND: 13675, 13676	12/17/14 AMEND: 51341.1
02/11/15	AMEND: 2643.5, 2643.10, 2643.15	12/01/14 REPEAL: 63000.10, 63000.13, 63000.16, 63000.17, 63000.19, 63000.25, 63000.28, 63000.31, 63000.34, 63000.35, 63000.37, 63000.40, 63000.43, 63000.46, 63000.47, 63000.48, 63000.49, 63000.62, 63000.65, 63000.66, 63000.67, 63000.68, 63000.70, 63000.71, 63000.74, 63000.77, 63000.80, 63000.81, 63000.83, 63000.84, 63000.85, 63000.86, 63000.87, 63000.88, 63000.89, 63000.90, 63000.92, 63000.95, 63010, 63011, 63012, 63013, 63014, 63015, 63020, 63021, 63025, 63026, 63027, 63028, 63029, 63030, 63040, 63050, 63051, 63052, 63055, 63056, 63057, 63058
02/05/15	AMEND: 6540	
01/21/15	ADOPT: 6550, 6551, 6553, 6553.1, 6555, 6557, 6557.1, 6557.2, 6557.3	
12/31/14	AMEND: 95802, 95830, 95833, 95852, 95852.2, 95890, 95892, 95895, 95921, 95973, 95975, 95976, 95981, 95983, 95985, 95990	
12/31/14	AMEND: 95201, 95202, 95203, 95204	
12/31/14	AMEND: 95101, 95102, 95103, 95104, 95111, 95112, 95113, 95114, 95115, 95119, 95121, 95122, 95124, 95130, 95131, 95132, 95133, 95152, 95153, 95156, 95157	
12/30/14	ADOPT: 30180.1, 30180.2, 30180.3, 30180.4, 30180.5, 30180.6, 30180.7, 30181, 30192.7, 30195.4, 30196, 30237, 30332.9 AMEND: 30180, 30190, 30192.1, 30194, 30195, 30195.2, 30195.3, 30235, 30253, 30254, 30257, 30330, 30332, 30332.5, 30332.6, 30332.8, 30333, 30333.1, 30334, 30336, 30336.1, 30336.5, 30346, 30346.2,	
		<b>Title 23</b>
		04/22/15 ADOPT: 600, 600.1, 600.2, 600.3, 600.4, 601, 602, 603, 603.5, 604, 605, 606, 607.1, 607.2, 607.3, 608.1, 608.2, 608.3,

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	610.1, 610.2, 610.3, 610.4, 610.5, 610.6, 610.7, 610.8, 610.9, 610.10, 610.11, 612.1, 612.2, 612.3, 612.4, 612.5, 612.6, 612.61, 612.62, 612.63, 612.64, 612.65, 612.66, 612.67, 615.1, 615.2, 615.3, 618, 620, 625.1, 625.2, 625.3, 625.4, 625.5, 625.6, 625.7, 635.0		AMEND: 1300.65, 1300.65.1
		<b>Title MPP</b>	
		01/23/15	AMEND: 11-403
		01/22/15	ADOPT: 42-708, 42-709 AMEND: 42-302, 42-701, 42-711, 42-712, 42-714, 42-716, 42-720, 42-721, 42-722, 42-802, 42-1009, 42-1010, 44-111
03/30/15	ADOPT: 877, 878, 878.1, 878.2, 879, 879.1, 879.2	12/12/14	ADOPT: 40-039 AMEND: 22-071, 22-072, 22-305, 40-103, 40-105, 40-107, 40-119, 40-125, 40-128, 40-173, 40-181, 40-188, 40-190, 41-405, 42-209, 42-213, 42-221, 42-406, 42-407, 42-716, 42-721, 42-751, 42-769, 44-101, 44-102, 44-111, 44-113, 44-115, 44-133, 44-205, 44-207, 44-211, 44-304, 44-305, 44-313, 44-315, 44-316, 44-318, 44-325, 44-327, 44-340, 44-350, 44-352, 48-001, 80-301, 80-310, 82-612, 82-812, 82-820, 82-824, 82-832, 89-110, 89-201
03/27/15	AMEND: 879(c)		
03/27/15	ADOPT: 863, 864, 865		
03/18/15	AMEND: 3939.10		
03/17/15	ADOPT: 3919.15		
02/17/15	ADOPT: 3919.14		
01/23/15	ADOPT: 3939.37		
01/05/15	ADOPT: 3946(b), 3946(c), 3946(d) AMEND: 3946(a)		
<b>Title 25</b>			
03/03/15	AMEND: 4514		
<b>Title 28</b>			
12/22/14	ADOPT: 1300.65.2, 1300.89.21		