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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 10. DEPARTMENT
OF INSURANCE**

ESSENTIAL HEALTH BENEFITS REGULATION

SUBJECT OF PROPOSED RULEMAKING

The Insurance Commissioner proposes to adopt the regulation described below after considering comments from the public. The Commissioner proposes to add to Title 10, Chapter 5, Subchapter 3 of the California Code of Regulations new Article 22, Essential Health Benefits, consisting of new Sections 2594, 2594.2, 2594.3, 2594.4, 2594.5, 2594.6, and 2594.7.

The proposed final regulation: (1) incorporates standards for coverage of essential health benefits from federal rules; (2) defines essential health benefits with more specificity than is present in statute; (3) clarifies the law applicable to prescription drug coverage and adopts filing requirements necessary to ensure compliance; (4) adopts a disclosure requirement for levels of coverage consistent with state and federal law; and (5) implements state law on levels of coverage through incorporating federal requirements concerning the mechanism of actuarial value calculation and enforcement for both health insurance policies and specialized health insurance policies that cover the pediatric oral essential health benefit.

PUBLIC HEARING

The Commissioner will hold a public hearing to provide all interested persons an opportunity to present statements or arguments, orally or in writing, with respect to the proposed regulations as follows:

Date and Time: January 13, 2014
10:00 a.m.
Location: San Diego Room
300 Capitol Mall, 2nd Floor
Sacramento, CA 95814

The hearing will continue on the date noted above until all testimony has been submitted or 4:00 p.m., whichever is earlier.

ACCESS TO HEARING ROOMS

The facilities to be used for the public hearing are accessible to persons with mobility impairments. Persons with sight or hearing impairments are requested to notify the contact person in order to make special arrangements, if necessary.

**PRESENTATION OF WRITTEN COMMENTS;
CONTACT PERSONS**

All persons are invited to submit written comments on the proposed regulations during the public comment period. The public comment period will end at **5:00 p.m. on January 13, 2014**. Please direct all written comments to the following contact person:

Jessica Ryan, Attorney
California Department of Insurance
45 Fremont Street, 21st Floor
San Francisco, California 94105
Telephone: (415) 538-4110
Email: Jessica.Ryan@insurance.ca.gov

Questions regarding procedure, comments, or the substance of the proposed action should be addressed to the above contact person. In the event the contact person is unavailable, inquiries regarding the proposed action may be directed to the following backup contact person:

Bruce Hinze, Senior Health Policy Attorney
California Department of Insurance
45 Fremont Street, 23rd Floor
San Francisco, California 94105
Telephone: (415) 538-4392
Email: HinzeB@insurance.ca.gov

DEADLINE FOR WRITTEN COMMENTS

All written materials must be received by the Insurance Commissioner, addressed to the contact person at her address listed above, no later than 5:00 p.m. on January 13, 2014. Any written materials received after that time may not be considered.

**COMMENTS TRANSMITTED BY EMAIL
OR FACSIMILE**

The Commissioner will accept written comments transmitted by email provided they are sent to the fol-

lowing email address: Jessica.Ryan@insurance.ca.gov. The Commissioner will also accept written comments transmitted by facsimile provided they are directed to the attention of Jessica Ryan and sent to the following facsimile number: (415) 904-5490. **Comments sent to other e-mail addresses or other facsimile numbers will not be accepted. Comments sent by e-mail or facsimile are subject to the deadline set forth above for written comments.**

AUTHORITY AND REFERENCE

The proposed regulations will implement, interpret, and make specific Insurance Code Section 10112.27 (Stats. 2012, ch. 866 (S.B. 951), as well as portions of sections 12 and 13 of Senate Bill 639 (Stats. 2013, ch. 316; to be codified at Insurance Code §§ 10112.295, 10112.297; effective January 1, 2014).

Insurance Code Section 10112.27(o) provides authority for this rulemaking, as do the following decisions of the California Supreme Court: *CalFarm Ins. Co. v. Deukmejian* (1989) 48 Cal.3d 805 and *20th Century Ins. Co. v. Garamendi* (1994) 8 Cal. 4th 216.

INFORMATIVE DIGEST

Summary of Existing Law

Senate Bill 951 (Stats. 2012, ch. 866) enacted California’s essential health benefit mandate into section 10112.27 of the Insurance Code in response to guidance issued by the United States Department of Health and Human Services (“HHS”) under the federal Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152) (“PPACA”). Subdivision (j) of Insurance Code section 10112.27 provides that the section shall not be implemented in a manner that conflicts with PPACA. The proposed regulation effectuates section 10112.27 through implementing the statute consistent with PPACA and a subsequent federal implementing regulation on essential health benefits.

Senate Bill 639 (Stats. 2013, ch. 316) enacted the other two components of the federal essential health benefits package, cost sharing restrictions applicable to essential health benefits and levels of coverage for essential health benefits, into state law on September 20, 2013. Sections 9, 10, 11, and 14 of S.B. 639, which enacted PPACA’s cost sharing restrictions into state law, are not discussed in this summary of existing law because the proposed regulation does not implement those portions of the law. The proposed regulation implements portions of sections 12 and 13 of S.B. 639, which

deal with levels of coverage for essential health benefits (to be codified at Ins. C. §§ 10112.295, 10112.297).

1) The Patient Protection and Affordable Care Act Established the Requirement to Provide the Essential Health Benefits Package

Section 2707(a) of the federal Public Health Service Act (42 U.S.C. § 300gg-6), added by PPACA, mandates that issuers of non-grandfathered individual and small group health insurance cover the essential health benefits package beginning in 2014.¹

Section 1302(a) of PPACA (42 U.S.C. § 18022(a)) defines the “essential health benefits package” as: (1) essential health benefits; (2) annual limitations on cost sharing for coverage of essential health benefits; and (3) statutorily-defined levels of coverage for essential health benefits, subject to an exception for catastrophic coverage.

Section 1302(b) of PPACA provides that essential health benefits are health care items and services within ten enumerated categories (ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care), and that the Secretary of HHS shall further define essential health benefits according to specific requirements.

Section 1302(c) of PPACA imposes annual limitations on cost sharing for essential health benefits. Section 1302(c)(1) establishes an annual limitation on cost sharing (out-of-pocket maximum) for individual and group health insurance products, determined in 2014 by the enrollee out-of-pocket limit for high deductible health plans under the Internal Revenue Code, and adjusted annually thereafter. Section 1302(c)(2) establishes an annual limitation on deductibles for small group health insurance products and provides for its annual adjustment.

Section 1302(d)(1) of PPACA defines the four levels of coverage in relation to actuarial value: platinum (90% actuarial value), gold (80%), silver (70%), and bronze (60%). Section 1302(d)(2) defines actuarial value relative to coverage of essential health benefits for a standard population. That section also provides that HHS will establish the details of the calculation of actuarial value by regulation. Finally, section 1302(e) provides for catastrophic plans in the individual market, the

¹Federal law speaks in terms of “health insurance issuer,” which is “an insurance company, insurance service, or insurance organization (including an HMO) that is required to engage in the business of insurance in a State and that is subject to State law that regulates insurance” (45 C.F.R. § 144.103.)

sole exception to the requirement that health insurance plans must provide one of the four “metal” levels of coverage.

2) *The Federal Essential Health Benefits Bulletin Established the Benchmark Approach and Formed the Basis for Section 10112.27 of the Insurance Code*

In December of 2011, the Center for Consumer Information and Insurance Oversight, a division of HHS, issued guidance describing its intended approach to defining essential health benefits. In the *Essential Health Benefits Bulletin*, HHS adopted a “benchmark approach” under which states would select a benchmark plan from among several types of plans designated in the bulletin. The benchmark plan serves as a reference plan, reflecting both the scope of services and any limitations on coverage in a typical plan offered by employers in the state. Insurance Code section 10112.27, signed into law on September 30, 2012, was enacted based on the benchmark approach described in the bulletin.

a) *The California approach: Insurance Code section 10112.27*

Subdivision (a) of section 10112.27 requires individual and small group health insurance policies to cover essential health benefits upon renewal, amendment, or issuance as of January 1, 2014 and defines essential health benefits in detail. Essential health benefits are defined to include all ten categories of essential health benefits enumerated in section 1302(b) of PPACA. (Ins. Code § 10112.27(a)(1).)

b) *The “base–benchmark” and “EHB–benchmark” plans*

The statute selected the Kaiser Foundation Health Plan, Inc. Small Group HMO \$30 Copayment Plan from among the options designated by HHS as California’s benchmark plan. (Ins. Code § 10112.27(a)(2)(A).) Under federal terminology, this benchmark plan is termed the “base–benchmark plan.” (See 45 C.F.R. § 156.20.) This term differentiates the base–benchmark plan from the “EHB–benchmark plan,” which is comprised of the benefits from the base–benchmark plan along with the benefits from the dental and vision plans chosen by the state to supplement the pediatric services category. (See 45 C.F.R. § 156.20.)

c) *Base–benchmark benefits*

Pursuant to section 10112.27, benefits covered by the base–benchmark plan as the plan was offered during the first quarter of 2012 are essential health benefits, including: medically necessary basic health care services, as defined in subdivision (b) of section 1345 of the Health and Safety Code and in section 1300.67 of Title 28 of the California Code of Regulations; the health benefits mandated to be covered by the base–bench-

mark plan pursuant to enumerated sections of the Health and Safety Code and section 1300.67.24 of Title 28 of the California Code of Regulations; and all other benefits covered by the base–benchmark plan that were not mandated benefits under state law. (Ins. Code § 10112.27(a)(2)(A).)

Insurance policies subject to section 10112.27 must comply with the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (“MHPAEA”). (Ins. Code § 10112.27(a)(2)(D).) Insurance policies subject to section 10112.27 must also comply with the state’s mental health parity law at section 1374.72 of the Health and Safety Code. (Ins. Code § 10112.27(a)(2)(A)(ii).)

For habilitative services, the statute provides that in addition to any benefits in that category which are covered by the base–benchmark plan, “coverage shall also be provided as required by federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA.” Habilitative services must be covered “under the same terms and conditions applied to rehabilitative services under the policy.” (Ins. Code § 10112.27(a)(3).) Habilitative services are defined in subdivision (q)(1) of section 10112.27.

d) *The “EHB–benchmark plan:” base, plus pediatric dental and vision*

For pediatric services, the *Essential Health Benefits Bulletin* provided that states could choose from either the Federal Employees Dental and Vision Insurance Program (FEDVIP) or the state’s Children’s Health Insurance Program (CHIP) to supplement the oral and vision benefits covered in that category. Section 10112.27 designated FEDVIP as the state’s supplemental benefits plan for pediatric vision benefits. (Ins. Code § 10112.27(a)(4).) Section 10112.27 designated the state’s Children’s Health Insurance Program, Healthy Families, as the state’s supplemental benefits plan for pediatric oral benefits. (Ins. Code § 10112.27(a)(5).)

e) *Other provisions of Insurance Code section 10112.27*

Subdivision (b) of section 10112.27 provides that limitations on coverage of essential health benefits shall be no greater than the limitations on coverage imposed by the base–benchmark plan, FEDVIP, and Healthy Families.

Subdivision (c) of section 10112.27 provides that “nothing in this section shall be construed to permit a health insurer to make substitutions for the benefits required to be covered under this section, regardless of whether those substitutions are actuarially equivalent.”

Subdivision (d) of section 10112.27 provides that, to the extent permitted pursuant to federal law, an insurer may use its prescription drug formulary rather than the base–benchmark plan’s formulary “as long as the cov-

erage for prescription drugs complies with the sections referenced in clauses (ii) and (iv) of subparagraph (A) of paragraph (2) of subdivision (a) that apply to prescription drugs.”

Subdivision (f) of section 10112.27 provides that the section applies “regardless of whether the policy is offered inside or outside the California Health Benefit Exchange. . . .”

Subdivision (g) of section 10112.27 provides that “[n]othing in this section shall be construed to exempt a health insurer or a health insurance policy from meeting other applicable requirements of law.”

Subdivision (i) of section 10112.27 provides that an individual or small group health insurance policy that provides excepted benefits as described in Sections 2722 and 2791 of the federal Public Health Service Act (42 U.S.C. § 300gg–21; 42 U.S.C. § 300gg–91) and an individual or small group health insurance policy that qualifies as a grandfathered health plan under Section 1251 of PPACA (42 U.S.C. § 18011) are not required to cover essential health benefits.

As noted above, subdivision (j) of section 10112.27 provides that “[n]othing in this section shall be implemented in a manner that conflicts with a requirement of PPACA.”

Subdivision (p) of section 10112.27 provides that “[n]othing in this section shall impose on health insurance policies the cost sharing or network limitations” of the benchmark plans. This means that the base–benchmark plan plays a role in defining benefits, but does not define other, non–benefit related, provisions of health insurance policies.

Finally, subdivision (q) of section 10112.27 provides definitions for terms used in the statute.

3) *The Federal Rule on Essential Health Benefits Implemented PPACA’s Essential Health Benefits Package*

On November 26, 2012, HHS issued the proposed rule on essential health benefits, which had a thirty–day comment period (77 Fed. Reg 70,644). HHS issued the final rule, *Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation*, on February 25, 2013, which became effective on April 26, 2013. (78 Fed. Reg. 12,834.) The requirement for issuers of individual and small group health plans to cover the essential health benefits package under section 2707(a) of the Public Health Service Act beginning in 2014 is codified in the federal regulations at section 147.150(a) of Title 45 of the Code of Federal Regulations. The bulk of the rule is dedicated to implementing the essential health benefits package, and is codified at Subpart B of Part 156 of Title 45 of the Code of Federal Regulations.

Section 156.100 codifies the options presented in the *Essential Health Benefits Bulletin* from which a state may select its base–benchmark plan.

Section 156.110 provides the standards for EHB–benchmark plans. Subsection (a) re–states the requirement for coverage of all ten essential health benefit categories described in PPACA section 1302(b). Subsection (b) provides for supplementation with benefits from CHIP or FEDVIP for pediatric oral and vision care. Subsection (d) provides that the state’s EHB–benchmark plan must meet the non–discrimination standards in the rule. Subsection (e) provides that the state may elect to define habilitative services, which determines the services that are included in that category.

Section 156.115 prescribes the requirements for providing essential health benefits under PPACA. Subsection (a)(1) requires a health plan to provide benefits that are “substantially equal to the EHB–benchmark plan including: (i) Covered benefits; (ii) Limitations on coverage including coverage of benefit amount, duration, and scope; and (iii) Prescription drug benefits that meet the requirements of § 156.122 of this subpart[.]” Subsection (a)(2) provides that, with the exception of the category for pediatric services, an enrollee may not be excluded from coverage in an essential health benefits category. Subsection (a)(3) provides that coverage of benefits for mental health and substance abuse disorder services, including behavioral health treatment services, must comply with the MHPAEA regulation at 45 C.F.R. section 146.136. Subsection (b) provides that unless prohibited by a state, an issuer may substitute actuarially equivalent benefits within the same essential health benefits category, and prescribes a method whereby the issuer must demonstrate actuarial equivalence to the state. Subsection (d) provides that “routine non–pediatric dental services, routine non–pediatric eye exam services, long–term/custodial nursing home care benefits, or non–medically necessary orthodontia” may not be classified as essential health benefits.

Section 156.122 provides standards for the coverage of prescription drugs. Subsection (a)(1) provides that a health plan must cover “at least the greater of: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the EHB–benchmark plan[.]” Subsection (a)(2) provides that an issuer must submit its drug list to the state.

Section 156.125 prohibits discrimination in benefit design, or in the implementation of benefit design. Subsection (a) prohibits discrimination “based on an individual’s age, expected length of life, present or predicted disability, degree of medical dependency, quality

of life, or other health conditions.” Subsection (b) prohibits discrimination based on race, color, national origin, disability, age, sex, gender identity or sexual orientation.

Section 156.130 implements PPACA’s annual limitations on cost sharing and small group market deductibles.

Section 156.135 provides methods for calculating actuarial value to determine a health plan’s level of coverage. Subsection (a) provides that, subject to the exception in subsection (b), an issuer must use the Actuarial Value Calculator developed by HHS to calculate the actuarial value of its health plans. Subsection (b) provides that if a health plan’s design is incompatible with the actuarial value calculator, the issuer must submit a certification of actuarial value to the state, prepared by an actuary, using one of two specified calculation methods. (See also 78 Fed. Reg. 12,834, 12,848–849 (February 25, 2013).) Subsection (c) provides that annual employer contributions to health savings accounts and amounts made available under health reimbursement arrangements must factor into the actuarial value for group plans.

Section 156.140 implements PPACA’s levels of coverage requirement. Subsection (a) provides that actuarial value, calculated as provided in section 156.135, determines whether a health plan offers a bronze, silver, gold, or platinum level of coverage. Subsection (b) defines the levels of coverage in relation to actuarial value (60%, 70%, 80%, and 90% actuarial value, respectively). Subsection (c) provides that a health plan meets a specific level of coverage if the actuarial value is within the range of plus or minus two percentage points from the given actuarial value for a level of coverage (e.g., an acceptable actuarial value for a bronze plan is in the range of 58–62%).

Section 156.150 provides rules for stand-alone pediatric dental plans, which under section 1311(d)(2)(B)(ii) of PPACA are limited-scope dental benefit plans certified by the Exchange that cover the pediatric oral essential health benefit. Subsection (a) provides that the issuer of a stand-alone pediatric dental plan must demonstrate to the Exchange that it has a reasonable annual limitation on cost sharing. Subsection (b)(1) provides that the Actuarial Value Calculator may not be used to calculate the actuarial value of a stand-alone pediatric dental plan. Subsection (b)(2) provides that the actuarial value for a stand-alone pediatric dental plan must be set at either 70% or 85% actuarial value, plus or minus two percentage points. Subsection (b)(3) provides that a stand-alone pediatric dental plan’s level of coverage must be certified by an actuary.

Section 156.155, added by another federal rule that was released at approximately the same time as the essential health benefits rule, implements PPACA’s cata-

strophic plan exception to the levels of coverage requirement. Catastrophic plans are the sole exception to the levels of coverage requirement, are available only in the individual market to individuals under age thirty or those who qualify for an exemption, and provide coverage for essential health benefits once a deductible equal to PPACA’s annual limitation on cost sharing is reached.

4) Senate Bill 639 Enacted Federal Levels of Coverage Rules Into State Law

Section 12 of S.B. 639, which is applicable to individual health insurance policies, enacts section 10112.295 into the Insurance Code as of January 1, 2014. Subdivision (a) of section 10112.295 defines levels of coverage: a bronze plan covers 60 percent of the cost of essential health benefits coverage, a silver plan 70 percent, a gold plan 80 percent, and a platinum plan 90 percent. As provided under federal law, subdivision (b)(1) specifies that the actuarial value of a plan may vary by only two percentage points from the designated actuarial value for a level of coverage (thus the actuarial value for a bronze plan may fall anywhere between 58–62 percent actuarial value). Subdivision (b)(2) provides that “[a]ctuarial value shall be determined on the basis of essential health benefits as defined in section 10112.27 and as provided to a standard, nonelderly population.” Actuarial value is measured as a percentage of anticipated health care costs a health plan pays for a standard population and is calculated based on the cost-sharing provisions for essential health benefits. (See definitions in 45 C.F.R. § 156.20.)

Subdivision (b)(3) authorizes the Department to “use the actuarial value methodology developed consistent with section 1302(d) of PPACA.” Subdivision (b)(3) refers to the federal actuarial value calculator developed by HHS to calculate actuarial value and the two methods for calculating the actuarial value of plans that are incompatible with the actuarial value calculator presented in 45 C.F.R. section 156.135. Subdivision (b)(4) provides that the “actuarial value for pediatric dental benefits, whether offered by a major medical policy or a specialized health insurance policy, shall be consistent with federal law and guidance applicable to the policy type.” Subdivision (b)(4) refers to the federal regulation on actuarial value and levels of coverage for stand-alone pediatric dental plans, which are dental plans certified by the Exchange that cover, at a minimum, the pediatric oral essential health benefit. (45 C.F.R. §§ 156.150, 155.1065.)

Section 13 of S.B. 639, which is applicable to small group health insurance policies, enacts section 10112.297 into the Insurance Code as of January 1, 2014. The relevant provisions of section 10112.297 are identical to those discussed above for section

10112.295. Additionally, subdivision (b)(6) provides that “[e]mployer contributions toward health reimbursement accounts and health savings accounts shall count toward the actuarial value of the product in the manner specified in federal rules and guidance.” Subdivision (b)(6) refers to 45 C.F.R. section 156.135(c), which specifies that annual employer contributions to health savings accounts (“HSA”) and amounts newly made available under health reimbursement arrangements (“HRA”) that may be used only for cost-sharing count towards the actuarial value of small group plans that are offered in conjunction with an HSA or integrated HRA.

5) Levels of Coverage Marketing Rules Under Insurance Code Section 10112.3

Subdivision (b) of Insurance Code section 10112.3 provides that “health insurers participating in the Exchange shall fairly and affirmatively offer, market, and sell in the Exchange at least one product within each of the five levels of coverage contained in subdivisions (d) and (e) of Section 1302 of the federal act.” While section 10112.3 equates catastrophic plans with a level of coverage, catastrophic plans are technically the sole exception to the levels of coverage requirement and may only be sold to certain consumers in the individual market. (For more state law on catastrophic plans, see Section 12 of S.B. 639, to be codified at Ins. C. § 10112.295(c).)

Subdivision (d) of Insurance Code section 10112.3 provides that “[c]ommencing January 1, 2014, a health insurer, with respect to policies that cover hospital, medical, or surgical benefits, may only sell the five levels of coverage contained in subdivisions (d) and (e) of Section 1302 of the federal act. . . .”

6) State Enforcement of PPACA

Finally, enforcement of the requirement to provide the essential health benefits package is governed by section 2723 of the federal Public Health Service Act. Under this enforcement scheme, states are primarily responsible for enforcement unless state regulatory agencies have not been granted statutory enforcement authority. If HHS determines that a state is not substantially enforcing PPACA’s market reforms, HHS is directly responsible for enforcement. (See 45 C.F.R. Part 150.) According to the Center for Consumer Information and Insurance Oversight, if a state does not have authority to enforce one or more provisions of PPACA, HHS will either enter a collaborative agreement for enforcement with any state that is willing and able to perform regulatory functions, or it will perform health insurance policy form review functions for any state that is unwilling to substantially enforce PPACA. Thus, consistent with Insurance Code section 10112.27(j), this proposed regulation assures that the Department can fully

enforce the essential health benefits package, as specified in the federal regulations, so as to avoid a circumstance where the federal government would become involved in the state’s health insurance policy review function.

Comparable Federal Law

As discussed above, existing federal statutes and regulations are comparable to the proposed regulations, including section 1302 of PPACA (42 U.S.C. § 18022) and portions of sections 156.20, 156.110, 156.115, 156.122, 156.125, 156.135, and 156.150 of Title 45 of the Code of Federal Regulations. The proposed regulations do not differ substantially from federal law.

Policy Statement Overview

The purpose of the proposed regulation is to interpret and make specific section 10112.27 of the Insurance Code, as well as to implement section 10112.27 in light of subsequent law on essential health benefits. Although Insurance Code section 10112.27 is a comprehensive statute that addresses many issues concerning California’s essential health benefits coverage mandate, many critical issues remain unresolved and thus require further specification. For example, section 10112.27 addresses only one element of the essential health benefits package, mandatory benefits. Other law on essential health benefits, including standards for coverage, cost-sharing restrictions applicable to essential health benefits, and levels of coverage for essential health benefits, is dispersed throughout state law and federal regulations.

The Department’s objective to implement section 10112.27 by incorporating subsequent state and federal law on essential health benefits is consistent with subdivision (j) of section 10112.27, which requires the Department to implement essential health benefits in a manner that does not conflict with PPACA. The proposed regulation incorporates provisions of the final federal regulation, *Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation*, which was proposed by HHS in November 2012 after the enactment of S.B. 951. The final federal regulation became effective on April 26, 2013 and is consequently not addressed in section 10112.27. For example, the federal regulation included a prescription drug coverage mandate that must be implemented by the state. The proposed regulation incorporates this new rule and addresses the procedure for enforcement. The proposed regulation also includes an explicit prohibition on discrimination in benefit design, or the implementation of benefit design, modeled after federal law. This provision prohibits a health insurer from designing its product to inhibit individuals with health conditions from enrolling or discriminating in coverage terms against insureds with particular health conditions. Adoption of

the anti-discrimination provision is necessary to prevent discrimination in a post-PPACA market in which insurers may no longer overtly deny individuals health insurance on the basis of preexisting medical conditions.

The proposed regulation also incorporates necessary changes to the emergency regulation text resulting from the enactment of Senate Bill 639 (Stats. 2013, ch. 316), which adopted, with some modifications, federal law on cost-sharing restrictions applicable to essential health benefits and levels of coverage for essential health benefits. Prior to the enactment of S.B. 639, the entire essential health benefits package (mandatory benefits, cost-sharing restrictions, and levels of coverage) had not been explicitly required by the Insurance Code. The portions of the emergency regulation requiring compliance with federal rules on coverage of the essential health benefits package, cost sharing, and levels of coverage have consequently been removed from the proposed permanent regulation, as state law on those topics will go into effect on January 1, 2014. The proposed regulation also incorporates some changes to the emergency regulation requiring demonstration of actuarial value to account for S.B. 639, which made federal law on actuarial value for stand-alone pediatric dental plans applicable to specialized health insurance policies (dental plans) that cover the pediatric oral essential health benefit.

Adoption of the proposed regulation is necessary for several reasons. First, the regulation provides coherent guidance regarding the essential health benefits coverage mandate and the process for demonstrating compliance with the levels of coverage requirement to the Department. Because the benchmark plan was a health care service plan subject to the Knox-Keene Act, section 10112.27 requires insurers to comply with state mandates that had never before been applicable to insurers. The proposed regulation enumerates the new mandates and other requirements in an organized fashion, making clear the body of law with which insurers must comply. Second, the proposed regulation makes some elements of the coverage mandate established by section 10112.27 more specific. For example, the regulation specifies the "other benefits" covered by the base-benchmark plan that were not otherwise required to be covered by state law, which are essential health benefits pursuant to section 10112.27(a)(2)(A)(v). Third, because the statute predated the final federal essential health benefits rule and S.B. 639, the proposed regulation is necessary to incorporate standards and procedures from those laws into the regulation, thereby enabling the Department to enforce them through the policy review process.

The benefits anticipated to result from adoption of the proposed regulation include: (1) the protection of pub-

lic health by ensuring that all non-grandfathered individual and small group health insurance policies cover essential health benefits at the levels of coverage required under state law and PPACA; (2) the promotion of government transparency in the health insurance policy review process by specifying the essential health benefits that individual and small group health insurers must cover, the standards for coverage, and the process through which the levels of coverage requirement in state and federal law will be enforced, including applicable compliance standards; (3) the promotion of efficiency in the policy review and approval process, which will confer benefits to the Department as well as health insurers that must comply with essential health benefits law; and (4) the promotion of consistency in coverage of essential health benefits and levels of coverage among health insurers regulated by the Department. Adoption of the proposed regulation will result in a benefit to the health and welfare of California residents by ensuring that the health insurance products they purchase include the consumer protections in state law that were enacted in response to federal health reform.

In conclusion, the proposed final regulation is essentially a road map for demonstrating compliance with essential health benefits requirements in health insurance policies submitted to the Department for review and approval prior to marketing. The proposed regulation incorporates elements of the final federal essential health benefits rule and S.B. 639 that must be implemented and enforced in California, elaborates on the requirements for coverage of essential health benefits, and establishes submission requirements and standards applicable to the preparation and review of health insurance policies for compliance with prescription drug law and the levels of coverage requirement for essential health benefits.

Consistency or Compatibility with Existing State Regulations

The Department has conducted an evaluation of existing state regulations and determined that the proposed regulations are not inconsistent or incompatible with any existing state regulations. While regulations promulgated by the California Health Benefit Exchange in Chapter 12 of Title 10 of the California Code of Regulations contain some terms, such as "essential health benefits," which are the subject of this regulation, the proposed regulations are not inconsistent or incompatible with those regulations. Consistent with Insurance Code section 10112.27(o)(3), the Commissioner, through Department staff, consulted with the Department of Managed Health Care in the development of this regulation. The Department of Managed Health Care issued an emergency regulation regarding essential health benefits on July 5, 2013 (OAL file number

2013–0635–02 E). On October 25, 2013, the Department of Managed Health Care issued notice for permanent rulemaking regarding essential health benefits (OAL notice file number Z2013–1015–04). The proposed regulation is not inconsistent or incompatible with the final regulation noticed by the Department of Managed Health Care.

MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The proposed regulations do not impose a mandate on local agencies or school districts. There are no costs to local agencies or school districts for which Part 7 (commencing with Section 17500) of Division 4 of the Government Code would require reimbursement.

COST OR SAVINGS TO STATE AGENCIES, LOCAL AGENCIES OR SCHOOL DISTRICTS, OR IN FEDERAL FUNDING

The Commissioner has determined that the proposed regulations will not result in a cost or savings to any other state agency, nor will it impose a cost on the Department of Insurance. The proposed regulations could produce efficiency improvements through streamlining the policy form review and actuarial value verification process, resulting in indeterminate savings.

The Commissioner has determined that the proposed regulations will not result in a cost or savings to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code. There is no other nondiscretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State.

ECONOMIC IMPACT ON BUSINESS AND THE ABILITY OF CALIFORNIA BUSINESSES TO COMPETE

The Commissioner has made an initial determination that the adoption of the proposed regulations 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 types of businesses that may be affected are health insurers. Compliance requirements include submitting information to the Department that insurers must already prepare for internal compliance purposes. The Commissioner has not considered proposed alternatives that would lessen an adverse economic impact on business and invites you to submit pro-

posals. Submissions may include the following considerations:

- (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
- (ii) Consolidation or simplification of compliance and reporting requirements for businesses.
- (iii) The use of performance standards rather than prescriptive standards.
- (iv) Exemption or partial exemption from the regulatory requirements for businesses.

POTENTIAL COST IMPACT ON PRIVATE PERSONS OR ENTITIES/BUSINESSES

The Commissioner is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed regulations. Similarly, health insurers will not incur any additional document preparation costs, as the information required to be filed by this proposed regulation is already prepared by insurance companies for other purposes.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Commissioner is required to assess any impact the regulations may have on the creation or elimination of jobs in the State of California, the creation of new businesses, the elimination of existing businesses, the expansion of businesses currently operating in the state, and the benefits of the regulation to the health and welfare of California residents, worker safety and the state's environment.

The Commissioner has made an initial determination that the proposed regulations will have no adverse economic impact on California's economy. The regulation is projected to have no effect on overall employment within the State of California (Government Code § 11346.3(b)(1)(A)). The creation of new businesses or the elimination of existing businesses within California will be unaffected by this regulation (Government Code § 11346.3(b)(1)(B)). The Department has determined that the proposed regulations do not impair the ability of California businesses to compete with businesses in other states (Government Code § 11346.3(b)(1)(C)). The proposed regulations will affect insurers, but, by law, insurers are not small businesses (Government Code § 11342.610(b)(2)). The proposed regulations will neither increase nor reduce worker safety. The Commissioner has also concluded that there will be no effect on the state's environment.

The Commissioner has determined that the proposed regulations will benefit California's individual and

small group health insurance consumers. The proposed regulations promote the health and welfare of California residents by ensuring that the health insurance policies they purchase cover essential health benefits at the levels of coverage required under state law. The proposed regulation also promotes efficiencies in the operation of insurance companies, as the regulations facilitate compliance, as well as commensurate efficiencies in the compliance operations of the Department.

FINDING OF NECESSITY

The Commissioner finds that it is necessary for the health, safety, or welfare of the people of the State that the proposed regulations apply to businesses.

IMPACT ON SMALL BUSINESS

The Commissioner has determined the proposed action will not affect small business as the regulations apply only to the conduct of insurers doing business in California, and pursuant to Government Code section 11342.610(b)(2), an insurer by definition is not a small business.

IMPACT ON HOUSING COSTS

The proposed regulations will have no significant effect on housing costs.

ALTERNATIVES

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

TEXT OF REGULATIONS AND STATEMENT OF REASONS

The Department has prepared an initial statement of reasons that sets forth the reasons for the proposed action. Upon request, the initial statement of reasons will be made available for inspection and copying. Requests for the initial statement of reasons or questions regarding this proceeding should be directed to the contact person listed above. Upon request, the final statement

of reasons will be made available for inspection and copying once it has been prepared. Requests for the final statement of reasons should be directed to the contact person listed above.

The file for this proceeding, which includes a copy of the express terms of the proposed regulation, the statement of reasons, the information upon which the proposed action is based, and any supplemental information, including any reports, documentation, and other materials related to the proposed action that is contained in the rulemaking file is available by appointment for inspection and copying at 45 Fremont Street, 21st Floor, San Francisco, California 94105, between the hours of 9:00 a.m. and 4:30 p.m., Monday through Friday.

MODIFIED LANGUAGE

If the regulations adopted by the Department differ from those which have originally been made available but are sufficiently related to the action proposed, they will be available to the public for at least 15 days prior to the date of adoption. Interested persons should request a copy of these regulations prior to adoption from the contact person listed above.

AUTOMATIC MAILING

A copy of this notice, including the informative digest, which contains the general substance of the proposed regulations, will automatically be sent to all persons on the Insurance Commissioner's mailing list.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Documents concerning these proposed regulations are available on the website of the Department of Insurance. To access them, go to <http://www.insurance.ca.gov>. Find at the right-hand side of the page the heading 'QUICK LINKS.' The third item in this column under this heading is 'For Insurers'; on the drop-down menu for this item, select 'Legal Information.' When the 'INSURERS: LEGAL INFORMATION' screen appears, click the third item in the list of bulleted items near the top of the page: 'Proposed Regulations.' The 'INSURERS: PROPOSED REGULATIONS' screen will be displayed. Select the only available link: 'Search for Proposed Regulations.' Then, when the 'PROPOSED REGULATIONS' screen appears, you may choose to find the documents either by conducting a search or by browsing for them by name.

To browse, click on the 'Currently Proposed Regulations' link. A list of the names of regulations for which documents are posted will appear. Find in the list the

link to ‘Essential Health Benefits (S.B. 951, permanent)’ and click it. Links to the documents associated with this regulation will then be displayed.

To search, enter “REG–2013–00015” (the Department of Insurance regulation file number for this regulation) in the search field. Alternatively, search by keyword (“essential health benefits,” for example). Then, click on the ‘Submit’ button to display links to the various filing documents.

TITLE 13. DEPARTMENT OF MOTOR VEHICLES

NOTICE IS HEREBY GIVEN

The Department of Motor Vehicles (department) proposes to adopt sections 227.00, 227.02, 227.04, 227.06, 227.08, 227.10, 227.12, 227.14, 227.16, 227.18, 227.20, 227.22, 227.24, 227.26, 227.28, 227.30, 227.32, 227.34, 227.36, 227.38, 227.40, 227.42, 227.44, 227.46, 227.48, 227.50 and 227.52 of Article 3.7, Title 13, California Code of Regulations, relating to autonomous vehicles.

PUBLIC HEARING

A public hearing has been scheduled to provide interested parties an opportunity to provide statements, both oral and in writing, on this proposed regulatory action. The department will hold the hearing beginning at 10:00 a.m. on Tuesday, **January 14, 2014**, at the department’s headquarters office at 2415 First Avenue, Sacramento, California.

The hearing will be held in the Assembly Room, which is accessible to persons with disabilities. The Assembly Room is located in a secure area of the building so please check in at the security station. Parking near the headquarters complex is limited, so please plan accordingly.

The public hearing will conclude when all attendees who wish to comment have provided their comment. If necessary, the department reserves the right to limit the length of time each participant has to comment.

DEADLINE FOR WRITTEN COMMENTS

Any interested party or his or her duly authorized representative may submit written comments relevant to the proposed regulations to the contact person identified in this notice. All written comments must be received at the department no later than 5:00 p.m., **JANUARY 13, 2014**, the final day of the written comment

period, in order for them to be considered by the department before it adopts the proposed regulations.

AUTHORITY AND REFERENCE

The department proposes to adopt the proposed action under the authority granted by Vehicle Code sections 1651 and 38750, in order to implement, interpret or make specific Vehicle Code sections 36590, 590, 672, 1808.1, 4000, 4150, 5902, 9255.1, 12810, 16000, 16053; Code of Civil Procedure section 995.010; Government Code sections 11110 through 11113, and 11500; Health and Safety Code section 43014; and Insurance Code section 1765.1.

INFORMATIVE DIGEST

Current law requires the department, upon application and payment of fees, to register vehicles that are being operated in the state. The department’s registration activities are administered by the Registration Operations Division. The department’s Licensing Operations Division is responsible for establishing occupational license application requirements and issuing occupational licenses or permits to applicants. It is also the department’s responsibility to ensure that all vehicles operating in California have insurance coverage, also known as financial responsibility. A driver is required to provide proof of financial responsibility when requested by law enforcement, when renewing a vehicle registration and in the event a vehicle is involved in an accident.

Senate Bill 1298 (Chapter 570; Statutes 2012) enacted California Vehicle Code section 38750 requiring the Department of Motor Vehicles to adopt regulations by January 1, 2015, setting forth requirements for the submission of evidence of insurance, surety bond or self-insurance, application approval process, and testing and safety requirements and the general operation of the vehicles on public roads. In an effort to ensure these regulations are promulgated as efficiently as possible, the department determined it necessary to implement the autonomous vehicle (AV) regulations in two separate regulatory actions. The first action implements financial responsibility requirements, the manufacturer testing application and permit process, reporting requirements and registration requirements.

After passage of AB 1298, the department quickly developed internal workgroups consisting of representatives from the department’s Licensing Operations Division and Registration Operations Division, and external workgroups including representatives from various state and federal agencies. The department also conducted two public workshops to get a better understanding of who the affected public stakeholder would be.

On April 19, 2013, the department conducted a general workshop in Sacramento. Attendees included rep-

representatives from AV technology manufacturers and vehicle manufacturers, as well as attendees representing academia, engineering, and public advocacy groups. The conversation was general in nature and allowed the department to interact with interested parties face to face to gain better knowledge of the public's concerns as we began this project.

On June 18, 2013, the department conducted a second workshop that was intended to address only the requirements provided in the first regulatory package. Specifically, the discussions were centered on the definitions, AV permit to test requirements, program requirements, establishing financial responsibility, accident reporting, and registration requirements. At this workshop, the department received helpful comments that assisted the department in drafting the regulatory text.

Both workshops were webcast and those webcasts have been posted to the department's website at <http://www.dmv.ca.gov/vr/autonomous/prevavrkrshp.htm>.

POLICY STATEMENT OVERVIEW

In considering how this program will function, the department has determined that the implementation of an autonomous vehicle tester permit would best meet the needs of the autonomous vehicle industry, as well as the needs of the department.

When a manufacturer submits to the department an application and payment of specified fees, the department will review the application to ensure there is evidence of financial responsibility, proof that an autonomous vehicle test driver training program is in place, verification of test vehicle requirements, and verification that the test driver meets specified requirements. Once the department verifies these requirements have been met, an autonomous vehicle tester permit will be issued to the manufacturer.

In creating this program, the department relied on models already being used by the department. For instance, the financial responsibility requirements are similar to those used in the occupational licensing branch and Business Partner Automation Program. The permit process is similar to that of the department's Motor Carrier Permit program whereby a permit holder is required to provide the department with evidence of financial responsibility and identify both drivers and vehicles on an annual basis. These programs operate very effectively and efficiently because of the comprehensive application process and ongoing oversight.

The department, by using the models of several successful programs, is confident that the autonomous vehicle program will be just as successful and allow manufacturers to continue to develop their technology

while ensuring the continued safety of the state's roadways.

PROBLEMS THIS DEPARTMENT INTENDS TO ADDRESS AND BENEFITS ANTICIPATED FROM THE REGULATORY ACTION

These regulations will make specific the requirements for the issuance of a permit to test autonomous vehicles on the public roadways of the State of California. These regulations specify how autonomous vehicle manufacturers are to submit evidence of financial responsibility as required by Vehicle Code section 38750(b)(3) as well as the process for applying for a permit to test the vehicles and the qualifications and training for autonomous vehicle test drivers. These regulations will allow automobile manufacturers and automobile researchers to develop and test automated vehicle driving systems on public roadways in a way that provides the assurance of safety to the public in general.

ALTERNATIVES CONSIDERED

The department initially considered approving AV testing through the issuance of registration documentation specifically identifying vehicles as being equipped with autonomous technology. If, under this model, a manufacturer failed to meet the testing requirements, the department would cancel the registration of the autonomous vehicles registered to that manufacturer.

After review of this model, the department determined it to be more beneficial and economical to establish a permit program that would allow the department to cancel the testing permit of a manufacturer that fails to comply with the testing requirements. This option allows the department to take one disciplinary action on the testing permit rather than multiple actions against each vehicle.

In considering this alternative, the department has determined that there is no reasonable alternative that would be more effective in carrying out the purpose for which the action is proposed, or would be effective as and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

COMPARABLE FEDERAL AND STATE REGULATIONS

The National Highway Traffic Safety Administration (NHTSA) establishes motor vehicle safety standards on the federal level. On May 30, 2013, NHTSA issued a "Preliminary Statement of Policy Concerning Automated Vehicles" to "help states implement this technol-

ogy safely so that its full benefits can be realized.” The NHTSA policy statement indicates that the U.S. Department of Transportation is researching the introduction of automated cars onto public roadways and advises states to leave safety standards up to federal regulators; however, to date, NHTSA has not adopted any regulations governing the testing or operation of automated, or self-driving, vehicles on public roads, streets, and highways.

There are no comparable federal or state regulations concerning the operation of autonomous vehicles on public roads.

CONSISTENCY EVALUATION

During the process of developing these regulations, the department 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.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents are incorporated by reference in the proposed regulatory text:

- Autonomous Vehicle Tester Program (AVT) Application for Manufacturer’s Testing Permit, form OL 311 (NEW 9/2013), in Section 227.26
- Autonomous Vehicle Testing (AVT) Program Test Vehicle Permit, form OL 313 (NEW 9/2013), in Section 227.48
- Autonomous Vehicle Testing (AVT) Program Test Vehicle Operator Permit, form OL 314 (NEW 9/2013), in Section 227.20
- Autonomous Vehicle Testing (AVT) Program Manufacturer Permit, form OL 315 (NEW 9/2013), in Section 227.28
- Report of Traffic Accident Involving an Autonomous Vehicle, form OL 316 (NEW 10/2013), in Section 227.44
- Autonomous Vehicle Manufacturer Surety Bond, form OL 317 (NEW 9/2013), in Section 227.10
- Autonomous Vehicle Testing (AVT) Program Application for Certificate of Self-Insurance, form OL 319 (NEW 9/2013), in Section 227.14

These documents are not published in the California Code of Regulations because it would be impractical and cumbersome to do so; however, these documents are readily available to interested parties by contacting the department representative identified below.

ECONOMIC AND FISCAL IMPACT DETERMINATIONS

The department has made the following initial determinations concerning the proposed regulatory action:

- Cost or Savings to Any State Agency: None.
- Other Non-Discretionary Cost or Savings to Local Agencies: None.
- Costs or Savings to Any Local Agency or School District: This proposed action will not impose any costs or savings on local agencies or school districts that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4, of the Government Code.
- Costs or Savings in Federal Funding to the State: None.
- Cost Impact on Representative Private Persons or Businesses: The department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- Effects on Housing Costs: None.
- Local Agency/School District Mandates: The proposed regulatory action will not impose a mandate on local agencies or school districts, or a mandate that requires reimbursement pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code.
- Small Business Impact: The proposed regulatory action may affect small business.
- Potential Significant Statewide 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.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The department states the following results of its Economic Impact Assessment per Government Code section 11346.3(b):

- Creation or Elimination of Jobs Within the State of California: This proposed regulation will neither create nor eliminate jobs within the State of California.
- Creation or Elimination of Existing Business Within the State of California: The proposed regulation will neither create new business nor eliminate existing business within the State of California.

- Expansion of Businesses Currently Doing Business Within the State of California: This regulation will not expand businesses currently doing business within the State of California.
- Benefits of Regulation to the Health and Welfare of California Residents, Worker Safety and the State's Environment: The proposed regulatory action is not likely to impact the health and worker safety or the environment. However, the proposed regulation intends to provide assurance of safety to the general public when technology manufacturers and researchers are developing and testing automated vehicle driving systems on public roadways.

PUBLIC DISCUSSIONS OF PROPOSED REGULATIONS

As identified in the Informative Digest, the department conducted two pre-notice workshops. The first workshop was held on April 19, 2013 and was general in nature. The second workshop was specific to the provisions identified in this proposed regulatory action. Both workshops were held pursuant to Government Code section 11346.45, because the issues involved are so complex that the department determined it necessary to engage the interested parties and other stakeholders as quickly as possible.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Brian G. Soublet, Assistant Chief Counsel
 Department of Motor Vehicles
 Legal Affairs Division
 P.O. Box 932382, MS C-244
 Sacramento, CA 94232-3820

Any inquiries or comments concerning the proposed rulemaking action requiring more immediate response may use:

Telephone: (916) 657-6469
 Facsimile: (916) 657-6243
 E-Mail: LRegulations@dmv.ca.gov

In the event the contact person is unavailable, inquiries should be directed to the following backup person:

Randi Calkins, Regulations Analyst
 Telephone: (916) 657-6469

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

The department has prepared an Initial Statement of Reasons for the proposed regulatory action, and has available all the information upon which the proposal is based. The contact person identified in this notice shall make available to the public upon request the Express Terms of the proposed regulatory action using underline or italics to indicate additions to, and strikeout to indicate deletions from the California Code of Regulations.

The contact person identified in this notice shall also make available to the public, upon request, the Final Statement of Reasons and the location of public records, including reports, documentation and other materials related to the proposed action. In addition, the above-cited materials (the Notice of Proposed Regulatory Action, the Initial Statement of Reasons, and Express Terms) may be accessed at <http://www.dmv.ca.gov/about/lad/regactions.htm>.

AVAILABILITY OF MODIFIED TEXT

Following the written comment period, and the hearing if one is held, the department may adopt the proposed regulations substantially as described in this notice. If modifications are made which are sufficiently related to the originally proposed text, the fully modified text, with changes clearly indicated, shall be made available to the public for at least 15 days prior to the date on which the department adopts the resulting regulations. Request for copies of any modified regulations should be addressed to the department contact person identified in this notice. The department will accept written comments on the modified regulations for 15 days after the date on which they are first made available to the public.

TITLE 16. BOARD FOR PROFESSIONAL ENGINEERS, LAND SURVEYORS, AND GEOLOGISTS

NOTICE IS HEREBY GIVEN that the Board for Professional Engineers, Land Surveyors, and Geologists (Board) is proposing to take the action described in the Informative Digest. The Board does not intend to hold a hearing in this matter. If an interested party wishes that a hearing be held, he or she must make the request in writing to the Board no later than 5 p.m. on December 30, 2013. The Board, 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 the Notice as the 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.

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 at its office no later than 5:00 p.m. on January 13, 2014.

Authority and Reference: Pursuant to the authority vested in Section 7818 of the Business and Professions Code, and to implement, interpret or make specific Sections 7800, 7801, 7802, 7802.1, 7803, 7803.1, 7804, 7804.1, 7822, 7841 and 7841.1, the Board is considering changes to Division 29 of Title 16 of the California Code of Regulations (CCR) as follows:

INFORMATIVE DIGEST

California Business and Professions Code (B&P) Section 7818 authorizes the Board to adopt, amend, and repeal regulations as may be reasonably necessary to enable the Board to implement laws relating to the practice of geology and geophysics.

The Board's intent is to ensure that all regulations are clear, relevant, unambiguous, and functional in accordance with the Board's 2011–2014 Strategic Plan.

The Board is proposing this regulatory action in order to clarify the definition of engineering geology and the definition of Professional Geophysical work. The Board's Geologist and Geophysicist Technical Advisory Committee (TAC), which is comprised of several licensed experts, made the determination that the definitions regarding engineering geology and Professional Geophysical work (Title 16, California Code of Regulations Section 3003(b) and (e)) require modification, and this determination was approved by the Board.

In accordance with Business and Professions Code Section 7826(c), the Board may establish a technical advisory committee or committees in order to advise the Board regarding the amendment, repeal, adoption, or revision of Board rules, regulations, policies, and procedures.

In accordance with Business and Professions Code Section 7826.2, all of the members of the technical advisory committee are licensed and are experts in geology and/or geophysics; therefore, the Geologist and Geophysicist TAC members have the knowledge to make the determination that changes should be made regarding the technical language of the definition regulations.

The proposed changes to Title 16, California Code of Regulations Section 3003 (b) and (e) were discussed over the course of several Geologist and Geophysicist TAC meetings with the added input of additional licensed Professional Geologists and Geophysicists.

The proposed changes are as follows:

- Title 16, California Code of Regulations Section 3003(b) — Definition Regarding Engineering Geology

Title 16, California Code of Regulations Section 3003(b) addresses the definition of engineering geology. Title 16, California Code of Regulations Section 3003(b) states that engineering geology includes “. . . the application of geologic data, principles and interpretation so that geologic factors affecting planning, design, construction and maintenance of civil engineering works are properly recognized and utilized.”

The proposed amendments include the addition of language that clarifies the role of an engineering geologist. The proposed amendments indicate that engineering geology is “. . . the application of geologic data, principles and interpretation so that geologic factors and processes affecting planning, design, construction, maintenance, and vulnerability of civil engineering works are properly recognized and utilized.”

The words “processes” and “vulnerability” have been added to create a more accurate definition of the engineering geology practice.

- Title 16, California Code of Regulations Section 3003(e) — Definition Regarding Professional Geophysical Work

Title 16, California Code of Regulations Section 3003(e) addresses the definition of Professional Geophysical work. A Professional Geophysicist is a licensed geophysicist pursuant to Business and Professions Code Section 7804.1. Title 16, California Code of Regulations Section 3003(e) indicates that Professional Geophysical work includes the following: work performed at a professional level; application of scientific knowledge; use of initiative and judgment; minimal supervision; professional responsibility; integrity; and “. . . investigating, measuring, interpreting and reporting on the physical phenomena of the earth.”

The subsection specifies that the following is not Professional Geophysical work: subprofessional/apprentice level work; work with little analysis of geological or geophysical work; work with lack of initiative; and work with a lack of scientific judgment.

The proposed amendment adds language regarding the scope of Professional Geophysical work, indicating that “The term includes the practice of geophysics for the evaluation and mitigation of earthquake hazards, and environmental and groundwater resources assessment.”

The purpose of this amendment is to create a more accurate definition of Professional Geophysical work in regards to the current scope of practice. In addition the amendment adds the subsections/scope of practice of geophysics that Business and Professions Code Section 7802.1 (“Geophysics” defined) does not define.

POLICY STATEMENT
OVERVIEW/ANTICIPATED BENEFITS
OF PROPOSAL

It is anticipated that the proposed changes will help depict a more accurate description in regards to the current scope of practice of engineering geology and Professional Geophysical work, and define the scope of Professional Geophysical work to include subsections of the practice that are currently not addressed in the definition. The regulation will benefit the public due to increased public health and safety. Accurately defining the scope of Professional Geophysical work clarifies what the practice entails for professionals in the field as well as for the public for the purposes of defining what kind of work can be performed by a Professional Geophysicist, and what may be considered unlicensed activity if the work/service is performed by an unlicensed individual, or an individual who does not possess the qualifications to perform the work/service.

Consistency and Compatibility with Existing State Regulations

After conducting a review for any regulations that would relate to or affect this area, the Board has evaluated this regulatory proposal and it is neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The proposed changes do not have an anticipated fiscal impact. The proposed changes to the definitions increase the accuracy of the true definition of the current scope of practice, but they do not change what is currently being done in the real world practices of engi-

neering geology and Professional Geophysics. As a result, the number of individuals who take the licensure exam(s) and apply for licensure after the passage of the exam(s) is not expected to increase or decrease; therefore, a fiscal impact is not expected.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

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

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board has determined that this proposed regulatory action will not have an 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.

Cost Impact on Representative Private Person or Business:

There is no anticipated cost impact to these individuals in the engineering geology and Professional Geophysics field that would occur as the result of clarifying the definition of engineering geology and Professional Geophysics. Therefore, the agency 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 Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses. The amendments to Title 16, California Code of Regulations Section 3003(b) and (e) update definitions regarding professions. The Board does not license businesses; the Board licenses individuals.

RESULTS OF ECONOMIC IMPACT
ASSESSMENT/ANALYSIS

Impact of Jobs/Businesses:

The Board has determined that this regulatory proposal will not have a significant 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:

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents, worker safety, and the State government:

The proposed changes will help depict a more accurate description in regards to the current scope of practice of engineering geology and Professional Geophysical work, and define the scope of Professional Geophysical work to include subsections of the practice that are currently not addressed in the definition. It is anticipated that the regulation will benefit the public due to increased public health and safety. Accurately defining the scope of Professional Geophysical work clarifies what the practice entails for professionals in the field as well as for the public for the purposes of defining what kind of work can be performed by a Professional Geophysicist, and what may be considered unlicensed activity if the work/service is performed by an unlicensed individual, or an individual who does not possess the qualifications to perform the work/service.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative is 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, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an Initial Statement of Reasons for the proposed action and has available all of 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 at 2535 Capitol Oaks Drive, Suite 300, Sacramento, CA 95833.

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 website listed below.

CONTACT PERSON

Inquires or comments concerning the proposed rulemaking action may be addressed to:

Name: Erin LaPerle
Address: 2535 Capitol Oaks Drive,
Suite 300
Sacramento, CA 95833
Telephone No.: (916) 263-1848
Fax No.: (916) 263-2246
E-mail Address: Erin.LaPerle@dca.ca.gov

The backup contact person is:

Name: Larry Kereszt
Address: 2535 Capitol Oaks Drive,
Suite 300
Sacramento, CA 95833
Telephone No: (916) 263-2240
Fax No.: (916) 263-2246
E-mail Address: Larry.Kereszt@dca.ca.gov

WEBSITE ACCESS

The Board's website is: <http://www.bpelsg.ca.gov/>. Materials regarding this proposal can be found at: http://www.bpelsg.ca.gov/about_us/rulemaking.shtml

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 January 13, 2014.

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 Department of Consumer Affairs, First Floor Hearing Room, 1625 N. Market Blvd, Sacramento, CA 95834, on January 16, 2014, at 10:30 a.m.

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

Authority and Reference. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 4057, 4127, and 4169 of the Business and Professions Code, the Board of Pharmacy is proposing to amend Articles 4.5 and 7 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, 1735.5 and Sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, 1751.9, 1751.10, 1751.11, 1751.12 as well as add Section 1751.9 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 com-

pounding 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.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Compounding pharmacies are 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.

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.

It is possible that regulation may occur at the federal level, pre-empting state law on this issue. The FDA has been working with Congress to craft legislation authorizing increased federal oversight of compounding pharmacies. The FDA asserts that there should be minimum federal standards for firms that compound sterile drug products in advance of or without a prescription and ship them interstate. The FDA also wants clear authority to proactively inspect pharmacies to determine the scope and nature of their operations. However, at this time, there are no such federal regulations. There are compounding professional standards that are used across the nation.

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).

Throughout the proposed text, there are amendments that occur in multiple places. In an effort to clarify these changes and eliminate redundancy in this document, they have been summarized below for consistency and nonduplication.

Multiple Occurrence of Amendment #1 — The board's proposal removes "injectable" and replaces the word with "drug" when referring to sterile injectable compounding. The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Multiple Occurrence of Amendment #2 — The purpose of the board's proposal replaces the phrase "expiration dating requirements" with "beyond use dating requirements." The purpose of the board's proposal is to ensure the board's regulations accurately reflect the USP 36 <797> Standard used in the compounding pro-

feSSION. While "expiration dating requirements" and "beyond use dating requirements" may seem simple and inconsequential, there is a distinct and drastic difference. The "expiration dating requirements" is provided by a manufacturer to indicate the chemical stability of the drug product. The "beyond use dating requirements" references the likelihood of contamination after removing from the manufacturer's original packaging and manipulating the substance. To use an everyday example, an "expiration dating requirement" for a can of corn may state it may be consumed a year from today. However, once that can of corn is opened, the "expiration date" is no longer a year from today as it has been opened and subjected to a different environment other than the manufacturer's original packaging. In the case of the can of corn, once the can is opened, the "expiration dating requirement" is no longer useful as it does not take into consideration temperature, atmospheric exposure or other similar factors. As such, a "beyond use dating requirements" is used once the original manufacturer's packaging has been opened to consider temperature, atmospheric exposure, and other such factors. While the can of corn is an oversimplified example, the concept remains the same. The "beyond use dating requirement" is used in the compounding industry because once the manufacturer's packaging has been opened and the drug product has been manipulated or exposed to an environment outside of the manufacturer's packaging, the likelihood of contamination increases. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Multiple Occurrence of Amendment #3 — The board's proposal removes old references and replaces them with updated and current references. The purpose is to update the following references:

- Chapter 797 of the United States Pharmacopeia — National Formulary (USP–NF) (35th Revision, Effective May 1, 2012) is updated to Chapter 797 of the United States Pharmacopeia National Formulary (USP36–NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013);

- 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 is updated to NSF International Standard/American National Standard for Biosafety Cabinetry — Biosafety Cabinetry: Design, Construction, Performance, and Field Certification [NSF/ANSI 49–2012], as revised July 7, 2012 (available from the Chair, Joint Committee on Biosafety Cabinetry c/o NSF International, P.O. Box 130140, 789 N. Dixboro Road, Ann Arbor, MI 48105, USA, phone number (734) 769–8010).

This change is necessary to ensure alignment and consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring the board’s regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products 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.

Multiple Occurrence of Amendment #4 — The board’s proposal removes the phrase “clean room” and replaces it with “cleanroom.” The purpose of the board’s proposal is to reflect the current and updated references throughout Articles 4.5 and 7 of Division 17 of Title 16 of the California Code of Regulations. The necessity of this change is to ensure alignment and consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in–state and nonresident pharmacies. 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.

Multiple Occurrence of Amendment #5 — The board’s proposal removes the phrase “from one or more non–sterile ingredients.” The purpose of the board’s proposal is to enhance the type of sterile drug products the regulations apply. By removing this text, the regulations apply to all sterile drug products and not only those sterile drug products “from one or more non–sterile ingredients.” This change is necessary to ensure consistency for all compounded drug products with sterile or non–sterile ingredients and not limit it to only those sterile drug products from one or more non–ster-

ile ingredients. The board’s proposal addresses the problem of ensuring patient safety for all who receive compounded drug products. 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.

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 is to remove the word “injectable” when referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

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

- The purpose of the board’s proposal to add subdivision (a) is to add a definition of “anteroom” for purposes of compounding drug products. The definition clarifies and specifies “anteroom” as an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, compounded sterile product labeling, and other high–particulate–generating activities are performed. It is a transition area that provides assurance that air flows from clean to dirty areas.
- The purpose of the board’s proposal to add subdivision (b) is to add a definition of “batch” for purposes of compounding drug products. The definition clarifies and specifies “batch” as more than one dose of a specific quantity of drug or other material that is intended to have uniform character and quality and is produced during the same continuous cycle of compounding.

- The purpose of the board’s proposal to add subdivision (c) is to add a definition of “beyond use date” for purposes of compounding drug products. The definition clarifies and specifies “beyond use date” as the date after which a compounded drug product should not be used.
- The purpose of the board’s proposal to add subdivision (d) is to add a definition of “buffer area” for purposes of compounding drug products. The definition clarifies and specifies “buffer area” as an area where the ISO Class 5 hood is physically located.
- The purpose of the board’s proposal to add subdivision (e) is to add a definition of “cleanroom” for purposes of compounding drug products. The definition clarifies and specifies “cleanroom” as a separate room meeting an ISO Class 7 or better air quality.
- The purpose of the board’s proposal to add subdivision (f) is to add a definition of “controlled cold temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled cold temperature” as 2° to 8° C (36° to 46° F).
- The purpose of the board’s proposal to add subdivision (g) is to add a definition of “controlled freezer temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled freezer temperature” as –25° to –10° C (–13° to 14° F).
- The purpose of the board’s proposal to add subdivision (h) is to add a definition of “controlled room temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled room temperatures” as 20° to 25° C (68° to 77° F).
- The purpose of the board’s proposal to amend subdivision (i) from subdivision (a) for the definition of “equipment” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (j) is to add a definition of “gloved fingertip sampling” for purposes of compounding drug products. The definition clarifies and specifies “gloved fingertip sampling” as the requirement that immediately after aseptic donning of sterile gloves compounding personnel will lightly press each fingertip and thumb onto appropriate growth media which will be incubated and then examined for growth of microorganisms.
- The purpose of the board’s proposal to amend subdivision (k) from subdivision (b) for the definition of “integrity” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (l) is to add a definition of “parenteral” for purposes of compounding drug products. The definition clarifies and specifies “parenteral” as a sterile preparation of drugs for injection through one or more layers of skin.
- The purpose of the board’s proposal to add subdivision (m) is to add a definition of “personal protective equipment” for purposes of compounding drug products. The definition clarifies and specifies “Personal protective equipment” as clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded sterile products and include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
- The purpose of the board’s proposal to amend subdivision (n) from subdivision (c) for the definition of “potency” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (o) is to add a definition of “process validation” for purposes of compounding drug products. The definition clarifies and specifies “Process validation” as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications using microbiological simulation of an aseptic process with growth medium processed in a manner similar to the normal order of production and with the same container or closure.
- The purpose of the board’s proposal to change subdivision (p) from subdivision (d) for the definition of “quality” is alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (q) is to add a definition of “segregated compounding area” for purposes of compounding drug products. The definition clarifies and specifies “segregated compounding area” as a designated space, either a demarcated area or room, that is restricted to preparing sterile-to-sterile compounded sterile products with a 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile products and shall be void of

activities and materials that are extraneous to sterile compounding.

- The purpose of the board’s proposal to add subdivision (r) is to add a definition of “smoke test” for purposes of compounding drug products. The definition clarifies and specifies “smoke test” as an analysis of the airflow in the ISO Class 5 hood using a smoke-generating device.
- The purpose of the board’s proposal to amend subdivision (s) from subdivision (e) for the definition of “strength” is for alphabetizing of the definitions and ease of readability.

These changes are necessary to ensure consistency 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. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <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.

Amend 16 CCR §1735.2

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The board’s proposal will add paragraph (4) to subdivision (c) to further define a “reasonable quantity” as not exceeding an amount the pharmacy can reasonably and safely compound. This change is necessary to further outline in regulation the requirement for compounding pharmacies compounding total volumes within their pharmacists’ and facility’s expertise. This addresses the problem of further clarifying reasonable quantity in the regulation to ensure the safety of Californians who receive compounded drugs from a compounding facility that is compounding within the facility’s ability to compound safely. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The board’s proposal will amend paragraph (3) of subdivision (d) by removing the phrase “expiration dating requirements” and replacing it with “beyond-use dating requirements.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #2” listed previously in this document. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The board’s proposal will amend subdivision (g) by removing “chemical, bulk drug substances.” This change is necessary to eliminate redundant words in regulation as the meaning of “chemical and bulk drug substance” is found within the remaining verbiage of “drug products and other components.” This addresses the problem of eliminating redundancy for ease of reading for the reader. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The board’s proposal will amend subdivision (h) by removing “expiration dating” and replacing “beyond use date.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #2” listed previously in this document. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The board’s proposal will amend subdivision (j) by removing “injectable” twice in the subdivision. The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565). Current law requires 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. This change is necessary to align the board’s compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Amend 16 CCR §1735.3

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

ressed the problem of ensuring the board's licensees understand the board's intent with regard to record-keeping. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The board's proposal will change paragraph (6) of subdivision (a) to include the updated version of the reference for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #3" listed previously in this document. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The board's proposal will amend paragraph (8) of subdivision (a) by removing "expiration" and replacing "beyond use." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #2" listed previously in this document. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The board's proposal will amend subdivision (c) to remove "components" twice and move the corresponding "and" in the list of items with removed "components." This change is necessary to eliminate redundancy as "components" is considered part of "chemicals, bulk drug substances, and drug products." The word "component" is redundant and addressed the problem of reducing confusion among the regulated licensees. The board's proposal will also amend subdivision (c) to require reliable suppliers of drug products for compounders to be FDA-registered. This change is necessary to add the requirement of "FDA-registered" to ensure that the supplier of drug products is adequately regulated by the Food and Drug Administration (FDA) and addressed the problem of the integrity of the purchased drug products by compounders providing compounded drug products to California consumers. The board's proposal further clarifies by deleting "any available" and adding requirements for certificates of purity or analysis to be matched to the product received. The requirement that all certifications of purity or analysis are to be kept and matched to the product received also includes the now required FDA-registered suppliers. This change is necessary to ensure a consolidated

record for a compounded drug product that may have multiple ingredients from multiple FDA-registered suppliers. This addresses the problem of clarifying the requirements of recordkeeping for certificates of purity and analysis of drug products. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The board's proposal will add subdivision (d) to specify after receipt by the pharmacy, packages of ingredients that lack a supplier's expiration date cannot be used after one (1) year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in compounded drug products. This change is necessary to identify for the board's regulated licensees the maximum time a drug product can be used without appropriate inspection or testing if the manufacturer failed to provide an expiration date. This addresses the problem of clarity to the board's regulated licensees and in accordance with compounding pharmacy professional standards USP 36 <797>. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The board's proposal will change subdivision (d) to (e) as a result of the newly created subdivision (d). This change is necessary to provide for the newly added subdivision (d) and ensure there are not two subdivisions in the same section entitled (e). This addresses the problem of eliminating confusion for the board's regulated licensees so that no section has two subdivisions with the same letter. 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.

Amend 16 CCR §1735.5

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will add to subdivision (a) the requirement that the pharmacy shall follow its policies and procedures and failure to follow these policies and procedures shall be deemed unprofessional conduct. This change is necessary to specifying the requirement of not only maintaining compounding policies and procedures but also a requirement to following the pharmacy's policies and procedures. A requirement to have compounding policies and procedures but not follow the policies and procedures is not consistent with the intent of the original regulation. This addresses the problem of the board being unable to enforce a requirement

to maintain and follow compounding policies and procedures where only the requirement to maintain was outlined in regulation. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will amend subdivision (c) to add a semicolon for the list of the subsequent requirements in paragraphs (1) through (7). This change is necessary to ensure the regulation is written in plain English. This addresses the problem of the board being accurate and clear to the board's regulated licensees. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will amend paragraph (4) of subdivision (c) to require documentation of the methodology be appropriate for the compounded drug products and to require this to be validated rather than tested. Additionally, the words "of compounded drug products" were stricken. This change is necessary to require documentation of the compounding formulas used for drug products compounded by the pharmacy. Additionally, "validate" is used instead of "test" to ensure that the compounded drug product's integrity, potency, quality, and labeled strength is corroborated rather than simply critically examined. The words "of compounded drug products" were stricken from the text as this was redundant with the addition of "appropriate to compound drug products." These changes address the problem of specifying and clarifying documentation requirements of methodology for the compounded drug product as well as clarifying the requirement of validation over testing of the compounded drug product. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will add paragraph (6) to subdivision (c) to require dates of annual reviews and signature/initials of the pharmacist-in-charge and dates of any revisions of policies and procedures. This change is necessary to clarify the times of reviews and documentation to verify the reviews have taken place. These changes address the problem of clarifying when and what is required at the time of review for the policies and procedures. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will amend paragraph (5) to subdivision (c) to delete "expiration" and replace with "beyond use." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #2" listed previously in this document. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will add paragraph (7) to subdivision (c) to require pharmacies that compound sterile drug products in the pharmacy at appropriate room, refrigerator, and freezer temperatures as required for each specific drug product as well as the daily documentation of these temperatures. This change is necessary to ensure that compounded drug products are stored at appropriate temperatures for the specific compounded drug product and to prevent contamination or bacterial or fungal growth in compounded drug products. Daily documentation ensures the pharmacy documents in adherence to this subdivision. These changes address the problem of clarifying that storage and daily documentation of compounded drug products is required at specified temperatures as outlined in referenced temperatures. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The board's proposal will add Business and Professions Code section 4301 to the reference cited for the regulation as failure for a pharmacy to follow its policies and procedures as outlined in subdivision (a) of section 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations is deemed unprofessional conduct. This change is necessary to ensure that the appropriate statute reference is cited. This change addresses the problem to ensure adherence to the Administrative Procedure Act. 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.

Amend 16 CCR §1751

Existing regulations at 16 CCR specify the title of Article 7 to be "Sterile Injectable Compounding." As a result of SB 294, the name of Article 7 will be changed to "Sterile Compounding." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.).

Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulation at 16 CCR specifies the title of §1751 to be "Sterile Injectable Compounding; Compounding Area; Self-Assessment" As a result of SB 294, the name of §1751 will be changed to "Sterile Compounding; Compounding Area; Self-Assessment." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board's proposal will amend subdivision (a) by striking "injectable" twice as a result of SB 294. The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board's proposal will amend subdivision (b) by striking "injectable" once as well as replacing in another part of the subdivision "injectable" with "drug" in accordance with SB 294. Additionally, subdivision (b) is split into two sentences for ease of readability and to clarify the standards apply to the environments within the pharmacy. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. This change is necessary to allow for easier readability of the regulation and to identify specifically the environment to which this subdivision pertains. The board's proposal addresses the problem of ensuring that board regulations are aligned with statute as well as be as clear as possible for the board's regulated licensees. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board's proposal will amend paragraph (1) of subdivision (b) to replace "clean room" with "cleanroom." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #4" listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board's proposal will amend paragraph (3) of subdivision (b) to replace "be" with "The pharmacy shall be." This change is necessary to specify that the requirement pertains to the pharmacy rather than an unidentified environment. The board's proposal addresses the problem of ensuring that board regulations are as clear as possible for the board's regulated licensees so that there is no confusion as to what is required to be ventilated. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board's proposal will amend paragraph (4) of subdivision (b) to replace "be" with "The ISO environment shall be" and "annually" is replaced with "at least six months." "Clean room" is replaced with "cleanroom." Additionally, "and whenever the device or cleanroom is relocated, altered, or a service to the facility is performed that would impact the

cleanroom or device.” is added. This change is necessary to specify that the certification pertains to the ISO environment rather than an unidentified environment. The change of certification requirements from annually to at least every six months and whenever the device or clean room is relocated, altered, or a service to the facility is performed that would impact the cleanroom or device is to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and non-resident pharmacies. The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #4” listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board’s proposal will amend paragraph (5) of subdivision (b) by replacing “injectable” with “drug.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board’s proposal will amend paragraph (6) of subdivision (b) by adding additional requirements that sinks and drains shall not be present in an ISO Class 7 or better cleanroom, in buffer area, nor adjacent to an ISO Class 5 hood in a segregated compounding area. A sink may be located in an anteroom. This change is necessary as sinks and drains are sources of contamination. In order to maintain a sterile environment for compounding, the sinks and drains may not be present in a cleanroom, buffer area nor adjacent to a hood in a segregated compounding area. Sinks may be located in an anteroom. When sterile compounding is being conducted, compounding tasks are done in an order to minimize contamination. Simultaneously, compounding tasks are also done in certain areas to minimize contamination. The board’s proposal addresses the problem to ensure that contamination does not occur in the sterile compounding area and the compounding

pharmacist is aware of where a sink and drain may or may not be located. Failure to do so would allow for a contamination source to be directly inside a sterile environment where sterile compounding is occurring for injection, inhalation or application to the eye by a California consumer. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The board’s proposal will amend subdivision (c) by replacing “injectable” with “drug.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Amend 16 CCR §1751.1

Existing regulation at 16 CCR specifies the title of §1751.1 to be “Sterile Injectable Recordkeeping Requirements.” As a result of SB 294, the name of §1751.1 will be changed to “Sterile Compounding Recordkeeping Requirements.” The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (a) by replacing “injectable” with “drug.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivi-

sion (b) by adding to sterile “compounded drug” products and striking “compounded from one or more non-sterile ingredients.” This change is necessary to ensure that sterile compounding regulations encompass drug products compounded from non-sterile to sterile ingredients as well as sterile to sterile ingredients. As the regulation is currently written, this only applies to drug products compounded from non-sterile to sterile. By including drug products compounded from sterile to sterile ingredients, the regulations are applied to all sterile compounding and not only drug products compounded from non-sterile to sterile ingredients. This change addresses the problem of regulations for sterile compounding being applied to those drug products compounded from non-sterile to sterile ingredients. The same regulations must apply to drug products compounded from sterile to sterile ingredients as well. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (b) to add a new paragraph (2) to require recordkeeping requirements for the results of gloved fingertip testing and aseptic technique media fill assessments. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (b) to add a new paragraph (3) to require recordkeeping requirements for the results of viable volumetric air and surface sampling. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these

compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (b) to renumber the former paragraph (2) to (4) and amend the paragraph to require recordkeeping requirements for the daily documentation of room, refrigerator, and freezer temperatures as appropriate for drug preparations consistent with the temperatures defined in section 1735.1. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (b) to renumber the former paragraph (3) to (5) regarding certification of the sterile compounding environment. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board’s proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board’s proposal will amend subdivision (b) to add a new paragraph (6) to require recordkeeping requirements for the logs of room pressure differentials. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding

standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board's proposal will amend subdivision (b) to renumber the former paragraph (4) to (7) regarding other facility quality control logs specific to the pharmacy's policies and procedures. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board's proposal will amend subdivision (b) to renumber the former paragraph (5) to (8) regarding inspections for expired or recalled pharmaceutical products or raw ingredients. The board's proposal will add an "s" to "Inspection" in order to require recordkeeping for all inspections rather than a singular inspection. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The board's proposal will amend subdivision (b) to renumber the former paragraph (6) to (9) regarding preparation records including master work sheet, the preparation work sheet, and records of end-product evaluation results. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Amend 16 CCR §1751.2

Existing regulation at 16 CCR specifies the title of §1751.2 to be "Sterile Injectable Labeling Requirements." As a result of SB 294, the name of §1751.1 will be changed to "Sterile Compounding Labeling Requirements." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Em-

merson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.2 specify requirements for sterile compounding labeling requirements. The board's proposal will amend the section by striking "injectable" and replacing it with "drug" three times throughout the section. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Amend 16 CCR §1751.3

Existing regulation at 16 CCR specifies the title of §1751.3 to be "Sterile Injectable Policies and Procedures." As a result of SB 294, the name of §1751.3 will be changed to "Sterile Compounding Policies and Procedures." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.3 specify requirements related to sterile compounding policies and procedures. The purpose of the board's proposal is to remove the word "injectable" when referring to sterile injectable compounding in §1751.3 subdivision (a) and paragraph (1) of subdivision (a). The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter

565.). Current law requires 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. This change is necessary to align the board's compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will amend the section by striking "injectable" and replacing it with "drug" five times throughout the section. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will add paragraph (5) of subdivision (a) to include in the policies and procedures the training of staff in the cleaning and maintenance of an ISO environment and segregated compounding areas. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will add paragraph (6) of subdivision (a) to include in the policies and procedures a viable and nonviable sampling plan. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the

problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and non-resident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will renumber paragraph (5) to (8) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will renumber paragraph (6) to (9) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will renumber paragraph (7) to (10) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will add paragraph (7) of subdivision (a) to include in the policies and procedures must documentation of the manufacturer's recommended purge time for barrier isolators. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations

for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and non-resident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will amend subdivision (d) by striking "from one or more non-sterile ingredients." This change is necessary to ensure that sterile compounding regulations encompass drug products compounded from non-sterile to sterile ingredients as well as sterile to sterile ingredients. As the regulation is currently written, this only applies to drug products compounded from non-sterile to sterile. By including drug products compounded from sterile to sterile ingredients, the regulations are applied to all sterile compounding and not only drug products compounded from non-sterile to sterile ingredients. This change addresses the problem of regulations for sterile compounding being applied to those drug products compounding from non-sterile to sterile ingredients. The same regulations must apply to drug products compounded from sterile to sterile ingredients as well. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will amend subparagraph (G) of paragraph (3) of subdivision (d) to strike "Regular" and replace with "Daily" cleaning and to add "and disinfection" schedule for controlled area of any equipment in the controlled area and to strike "and the alternation of disinfectants" and replace with "as specified in section 1751.4." This will also strike "subdivision" and replace with "subparagraph" as the reference in current regulation was incorrect. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and non-resident pharmacies. This is a real benefit to the people of the State of California particularly when the protec-

tion of public health and safety, worker safety, or the environment is involved.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will amend subparagraph (I) of paragraph (3) of subdivision (d) to enhance the requirement for sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets by striking ", and for" and adding ", and for sterility and bacterial endotoxin testing." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will move the contents of subparagraphs (J) and (K) of paragraph (3) of subdivision (d) to a new subparagraph (J) entitled "For non-sterile to sterile compounding" of paragraph (3) of subdivision (d). This change is necessary to clarify the requirements of policies and procedures for non-sterile to sterile compounding to include sterilization and end-product evaluation and testing. The board's proposal addresses the problem of ensuring clarity for the board's regulated licensees and reducing such discrepancy for the compounding profession who are compounding drug products in California and shipped 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The board's proposal will add a new subparagraph (K) of paragraph (3) of subdivision (d) to add the requirement for policies and procedures for action levels of colony-forming units (CFUs) detected during viable surface testing and volumetric air sampling. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal ad-

dresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.4

Existing regulation at 16 CCR specifies the title of §1751.4 to be "Facility and Equipment Standards for Sterile Injectable Compounding." As a result of SB 294, the name of §1751.3 will be changed to "Facility and Equipment Standards for Sterile Compounding [from Non-Sterile Ingredients]." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will amend the section by striking "injectable" and replacing it with "drug" two times throughout the section and striking "injectable" from "sterile injectable drug products" one time. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will add subdivision (d) to specify cleaning and disinfecting surfaces in the ISO Class 5 hood shall occur frequently, including: at the beginning of each shift; before each batch; every 30 minutes during continuous compounding of individual compounded sterile drug products; after each spill; when surface contamination is known or

suspected; and when switching between cytotoxic and non-cytotoxic ingredients. This change outlines minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will renumber subdivision (d) to (e) and strike "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." and replace with "Counters, cleanable work surfaces and floors shall be cleaned and disinfected daily. Walls, ceiling, storage shelving, tables and stools are to be cleaned and disinfected monthly. Cleaning shall occur after any unanticipated event that could increase the risk of contamination. Cleaning shall include the periodic use of a sporicidal agent." This change outlines minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will renumber subdivision (e) to (f) and specifically delete "parenteral" and replace with "sterile" when referring to phar-

macies preparing sterile cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Administrative Code requiring a laminar air flow hood. Additionally, the board's proposal will change the hood certification from annually to every six months. The board's proposal updates the reference and contact information for the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry to NSF International Standard/American National Standard for Biosafety Cabinetry — Biosafety Cabinetry: Design, Construction, Performance, and Field Construction. The board's proposal removes the requirement that certification records must be retained for at least three years and specifies that the hood shall be decontaminated when switching between cytotoxic and non-cytotoxic ingredients. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #3" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will add subdivision (g) to specify that pharmacies preparing sterile cytotoxic agents shall use a biological safety cabinet or compounding aseptic containment isolator that provides an ISO Class 5 environment during dynamic compounding conditions which is maintained in accordance with the manufacturer's recommendations and which is certified every six months. If a compounding aseptic containment isolator meeting the above criteria is located outside of an ISO Class 7 area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 air changes per hour. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements to prevent worker inhalation or contamination if cytotoxic (chemotherapy) air escapes the controlled environment of the biological safety cabinetry or compounding aseptic containment

isolator. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The board's proposal will add subdivision (h) to specify that viable surface and volumetric air sampling by impaction shall occur at least every six months by a qualified technician 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. Exceeded action levels shall prompt an immediate investigation of cleaning and compounding operations and facility management. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.5

Existing regulation at 16 CCR specifies the title of §1751.5 to be "Sterile Injectable Compounding Attire." As a result of SB 294, the name of §1751.3 will be changed to "Sterile Compounding Attire." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will delete subdivision (a) removing the requirement for gowns and gloves to be worn when preparing cytotoxic agents. The section is further expanded with the addition of requirements for gowns and gloves to be worn for all sterile compounding and not only compounding of cytotoxic agents. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will renumber subdivision (b) to (a). The new subdivision (a) will provide for the standards that must be met when compounding sterile drug products. The board's proposal will add "drug" so that compounding sterile products is now compounding sterile drug products. The board's proposal will also remove "from one or more non-sterile ingredients." This change is necessary to add "drug" and further specify that compounded sterile products referenced in this section apply to compounded sterile drug products rather than other types of products such as food. The board's proposal addresses the problem of ensuring that board regulations are clear to the board's regulated licensees. Additionally, the necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #5" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will amend paragraph (1) of subdivision (a) to specify cleanroom garb requirements. Specifically, the "low-shedding coverall" is revised to a "non-shedding gown." The change is required to prevent particles from the gown worn during compounding to fall off the gown and into the compounded drug products. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and non-resident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will amend paragraph (2) of subdivision (a) to specify where cleanroom garb must be donned and removed. Specifically, "in an anteroom" is added to where cleanroom garb must be donned and removed. Additionally, "outside the designated area" is removed and "in a designated area immediately outside the segregated compounding area" is added as the other option to where cleanroom garb must be donned and removed. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will add paragraph (3) of subdivision (a) to specify the donning of personal protective equipment. Specifically, "Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. 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 and then the donning of a non-shedding gown. Cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves must occur within the buffer area, not prior to entering. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol after contact with non-sterile objects.” This change is required to further clarify and specify for the board’s regulated licensees the requirement for personal protective equipment during the sterile compounding of drug products. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board’s proposal will renumber paragraph (3) to (4) of subdivision (a) to specify where what personal property may be worn by compounding personnel. Specifically, the paragraph is revised by making grammar changes and deleting “must be eliminated” to read “Compounding personnel shall not wear hand, finger, or wrist jewelry. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove,” is added as the other option to where cleanroom garb must be donned and removed. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board’s proposal will delete the former paragraph (4) of subdivi-

vision (a) to specifically remove “Head and facial hair must be kept out of the critical care area or be covered.” This change is necessary in that it is redundant with the requirement set forth in paragraph (1) of subdivision (a). Further, this change aligns the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board’s proposal will amend paragraph (5) of subdivision (a) to specify sterile glove requirements. Specifically, the paragraph is revised by deleting “Gloves made of low-shedding materials are required.” and replacing with “Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.” This is required in order to ensure that the gloves used by compounding personnel do not interact with isopropyl alcohol as isopropyl alcohol is the product used for disinfection. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board’s proposal will add paragraph (6) of subdivision (a) to specify that “Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from working in ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.” This is required to protect both the compounding per-

sonnel from contamination with open wounds on their body as well as protect the consumer of California receiving the compounded drug product to ensure that bodily fluids are not included in the compounded drug product. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will delete subdivision (c) specifically deleting "The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients." The purpose of the board's proposal is to enhance the type of sterile drug products the regulations apply. By removing this text, the regulations apply to all sterile drug products and not only those sterile drug products "from one or more non-sterile ingredients." This change is necessary to ensure consistency 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. The board's proposal addresses the problem of ensuring patient safety for all who receive compounded drug products. 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.

Existing regulations at 16 CCR §1751.5 specify requirements for sterile compounding attire. The board's proposal will add subdivision (b) to specify "When preparing cytotoxic agents, appropriate gowns and personal protective equipment shall be worn." This further specifies that in addition to the compounding attire outlined in subdivision (a), compounding personnel must ensure appropriate personal protective equipment for cytotoxic agents is donned when preparing cytotoxic agents. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures

the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.6

Existing regulation at 16 CCR specifies the title of §1751.6 to be "Training of Sterile Injectable Compounding Staff, Patient, and Caregiver." As a result of SB 294, the name of §1751.3 will be changed to "Training of Sterile Compounding Staff, Patient, and Caregiver." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend the section by striking "injectable" and replacing it with "drug" three times throughout the section and striking "injectable" from "sterile injectable drug products" one time. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend the subdivision (a) to add ", storage, handling, and disposal" to the requirements for consultation and will be stated as "Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable drug products and related supplies furnished by the pharmacy." This change is necessary to provide for increased consultation to be provided to the patient and/or primary caregiver. This will assist the patient and/or primary caregiver by increasing the information provided re-

lated to the proper use, storage, handling, and disposal of compounded sterile drug products. The problem addressed is to increase knowledge for the consumers of California with regard to the compounded sterile products they inject, inhale and apply to their eyes. Increased information assists with medication compliance as well as reduces the number of medication errors with regards to medication compliance. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend subdivision (e) to remove "from one or more non-sterile ingredients." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #5" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend subparagraph (E) of paragraph (1) of subdivision (e) to add additional information to the aseptic preparation procedures. Specifically, the subparagraph will read as "Aseptic preparation procedures using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the compounding process." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend subparagraph (I) of paragraph (1) of subdivision (e) to add additional information to the sterilization techniques. Specifically, the subparagraph will read as "Sterilization techniques for compounding sterile drug products from one or more non-sterile ingredients." This change is necessary to align the board's com-

pounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The board's proposal will amend paragraph (2) of subdivision (e) to add additional information to the requirement outlining who of the compounding personnel must complete practical skills training in aseptic technique and aseptic area practices. Specifically, the board's proposal strikes "assigned to the controlled area" and replaces with "who handles compounded sterile drug products" so that the paragraph will read as "Each person who handles compounded sterile drug products must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years." In addition to enhancing worker competency and safety, this change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.7

Existing regulation at 16 CCR specifies the title of §1751.7 to be "Sterile Injectable Compounding Quality Assurance and Process Validation." As a result of SB 294, the name of §1751.3 will be changed to "Sterile Compounding Quality Assurance and Process Valida-

tion.” The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will amend the section by striking “injectable” six times and replacing it with “drug” four times throughout the section. The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will amend paragraph (1) of subdivision (a) to delete “parenteral medication” and replace with “sterile” so that the paragraph reads “Cleaning and sanitization of the sterile preparation area.” This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will delete paragraph (2) of subdivision (a) as this has been moved to 16 CCR §1751.1 entitled Sterile Compounding Recordkeeping Requirements. This change is necessary

for ease of readability for the board’s regulated licensees as this documentation requirement has been moved to the section for recordkeeping. The board’s proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will renumber paragraph (3) to (2) of subdivision (a) as a result of deleting the former paragraph (2) of subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board’s proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will renumber paragraph (4) to (3) of subdivision (a) as a result of deleting the former paragraph (2) of subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board’s proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will amend paragraph (4) of subdivision (a) by removing “expiration dating requirements” and replacing “beyond use dating requirements.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #2” listed previously in this document. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board’s proposal will amend subdivision (b) to remove the following text “The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare.” and replace the text to read “The validation process shall be as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the compounding process.” This requires the

validation process to be as extreme as the most difficult compounding manipulation performed at the pharmacy. The board's proposal will also increase the requirement of the medium samples to be incubated by adding "in a manner consistent with the manufacturer's recommendations and demonstrated to promote growth." This requires the compounding pharmacy to follow the manufacturer's guidelines to ensure the validation is being conducted according to manufacturer's standards. The board's proposal increases the requirement for personnel competency's re-evaluation at least every twelve months by adding "for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients." This requires those compounding from non-sterile products to sterile products to be tested twice a year. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board's proposal will add subdivision (c) to read as follows: "All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units) at least three times before initially being allowed to compound sterile drug products." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board's proposal will add subdivision (d) to read as follows: "Re-evaluation of garbing and gloving competency shall occur at least annually for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board's proposal will renumber subdivision (c) to (e) as a result of adding subdivisions (c) and (d). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. The purpose of the board's proposal is to include references for Chapter 71 of the United States Pharmacopeia-National Formulary and Chapters 85 and 151 of the United States Pharmacopeia-National Formulary. This change is necessary to ensure that the most current and up-to-date citations are referenced in the board's regulation. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring the board's regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products 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. The board's proposal additionally clarifies the requirements for end product testing confirming sterility and acceptable levels of pyrogens to be before dispensing. This is to ensure that contaminated compounded drug products are not dispensed to California consumers. Additionally, the board's proposal requires samples for sterility testing to be taken at the beginning, middle and end of the compounding process. This change is necessary to ensure testing is done

on compounded drug products compounded throughout the entire process to ensure sterility and acceptable levels of pyrogens prior to dispensing to California consumers. The board's proposal addresses the problem of ensuring the board's regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products in California.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The board's proposal will renumber subdivision (d) to (f) as a result of adding subdivisions (c) and (d). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Amend 16 CCR §1751.8

The amended and proposed regulation at 16 CCR specifies the title of §1751.8 to be "Beyond Use Dating for Sterile Compounded Drug Products." The board's proposal will outline for the board's regulated licensees conducting sterile compounding the requirement for every compounded drug product to be given and labeled with a beyond-use date. Subdivisions (a), (b), (c), and (d) outline beyond-use date requirements for sterile compounded drugs compounded solely with aseptic manipulations meeting the outlined specifications. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Add 16 CCR §1751.9

The proposed regulation at 16 CCR specifies the title of §1751.9 to be "Single-Dose and Multi-Dose Containers; Limitations on Use." The board's proposal will outline the requirements for the use of single-dose containers in accordance with the usage and intended use of one time when meeting the outlined requirements. The board's proposal will also outline the restriction of a multi-dose container absent the manufacturer's specifications. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment

ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Renumber 16 CCR §1751.8 to §1751.10

Existing regulation at 16 CCR specifies the title of §1751.8 to be "Sterile Compounding Reference Materials." The board's proposal will make a nonsubstantive change and renumber the section from 1751.8 to 1751.10 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.10 to §1751.11

Existing regulation at 16 CCR specifies the title of §1751.10 to be "Furnishing to Parenteral Patient at Home." The board's proposal will make a nonsubstantive change and renumber the section from 1751.10 to 1751.11 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.11 to §1751.12

Existing regulation at 16 CCR specifies the title of §1751.11 to be "Furnishing to Home Health Agencies and Licensed Hospices." The board's proposal will make a nonsubstantive change and renumber the section from 1751.11 to 1751.12 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.12 to §1751.13

Existing regulation at 16 CCR specifies the title of §1751.12 to be "Obligations of a Pharmacy Furnishing Portable Containers." The board's proposal will make a nonsubstantive change and renumber the section from 1751.12 to 1751.13 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Based on an initial evaluation, the board does not believe that the proposed regulation is inconsistent or 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.

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 USP 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 themselves have any effect on the (1) creation or elimination of jobs within the State of California, (2) creation of new businesses or the elimination of existing businesses within the State of California, or (3) expansion of businesses currently doing business within the State of California. The board does not have any information indicating the adoption of proposed amendments to Articles 4.5 and 7 would actually have a positive effect on the creation of jobs and new businesses within California and the expansion of businesses currently doing business in California. Consideration by the board as to whether the benefit to the consumers of California outweighs any negative effect on affected businesses is not anticipated to eliminate jobs or existing businesses. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice and are consistent with compounding industry standards.

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

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

Elimination of Existing Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the elimination of existing businesses in the State of

California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

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

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

Occupations/Businesses Impacted: The Board of Pharmacy has made an initial determination that this regulatory proposal will impact pharmacies and specialty sterile compounding pharmacies. As of July 2013, the board had approximately 6,900 pharmacies (sites) with current licenses issued by the board. Of those 6,900 pharmacies, the board issued approximately 389 specialty sterile compounding permits.

Reporting Requirements: None.

Comparable Federal Regulations: None.

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

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

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its

attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

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

INITIAL STATEMENT OF REASONS AND INFORMATION

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

TEXT OF PROPOSAL

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

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

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

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

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Debbie Damoth
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Telephone No.: (916) 574-7935
Fax No.: (916) 574-8618
E-mail Address: Debbie.Damoth@dca.ca.gov

The backup contact person is:

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

INFORMATIVE DIGEST

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

TITLE 16. DENTAL HYGIENE COMMITTEE OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Delta Hygiene Committee of California (Committee) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the:

Department of Consumer Affairs
 1st Floor Hearing Room
 2005 Evergreen Street
 Sacramento, California on

January 15, 2014

10:00 a.m.

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 Committee at its office not later than 5:00 p.m. on January 15, 2014, or must be received by the Committee at the hearing. The Committee, 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 sections 123, 496, 1905, 1906, and 1917 of the Business and Professions Code, and to implement, interpret or make specific sections 1902, 1905, 1908, 1909, 1910, 1911, 1917, 1918 and 1922 of the Business and Professions Code, the Committee is considering changes to Division 11 of Title 16 of the California Code of Regulations as follows:

A. Informative Digest

The Committee currently regulates a total of 31,154 licensees, consisting of 30,636 registered dental hygienists, 480 registered dental hygienists in alternative practice and 38 registered dental hygienists with extended function. The Committee's highest priority is the protection of the public when exercising its licensing, regulatory, and disciplinary functions. The Committee issues licenses to eligible applicants, investigates complaints against licensees, disciplines licensees for violation of the Business and Professions Code Sections 1900-1966.6 and monitors licensees who are on probation.

Business and Professions Code Section 1906 authorizes the Committee to adopt, amend and repeal such rules and regulations as may be reasonably necessary to enable the Committee to effect the provisions of Business and Professions Code 1900-1966.6.

The main purpose of this proposal is to specify definitions for various terms used in statute, allow the Committee to delegate certain functions to its Executive Officer, and provide clarification of procedures, criteria and the appeals process relative to written and clinical examinations. The Committee is currently utilizing the Dental Board's regulations in these areas; however many of those existing regulations relative to dental hygiene no longer conform to more recent statutory law.

The Committee is proposing the following:

- Adopt Section 1100 of Division 11, Title 16 of the California Code of Regulations This proposed section defines dental hygiene terms that are used within statute in regulation so that applicants, licensees, staff and the public have clear and consistent definitions for terms currently in statute or that are used in dental hygiene practice.
- Adopt Section 1101 of Division 11, Title 16 of the California Code of Regulations This proposed section allows the Committee to delegate specific functions to its Executive Officer to assist the timely progress of investigative and administrative proceedings and the initiation of accusations and statements of issues. The objective of this proposal is to enhance the efficiency and timeliness of the Committee's investigations and enforcement.
- Adopt Section 1121 of Division 11, Title 16 of the California Code of Regulations This proposed section specifies that the written Law and Ethics examination required of all applicants will be tailored to the respective license category and lists the pass point. The objective of this proposal is to inform applicants of the nature of the examination

and the pass point to achieve successful completion.

- Adopt Section 1122 of Division 11, Title 16 of the California Code of Regulations This proposed section specifies that for written examinations, applicants must be able to read and interpret instructions and examination materials, and directs applicants to Section 123 of the Code for the reasons for dismissal from an examination.
- Adopt Section 1124 of Division 11, Title 16 of the California Code of Regulations This proposed section specifies that applicants for the Committee’s clinical examination must provide patients, instruments and materials necessary for the examination, and supplies criteria for patient selection. The objective of this proposed language is to inform applicants of the procedures and requirements of the clinical examination.
- Adopt Section 1126 of Division 11, Title 16 of the California Code of Regulations This proposed section specifies the conduct of clinical examinations to ensure that the examination will be anonymous.
- Adopt Section 1127 of Division 11, Title 16 of the California Code of Regulations This proposed section specifies the appeals process for the benefit of applicants who have failed the clinical examination.
- Adopt Section 1133 of Division 11, Title 16 of the California Code of Regulations This proposed section clarifies that licensees must adhere to the Minimum Standards for Infection Control and references the specific section of law.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The Committee’s policy is to promulgate regulations for the protection of California consumers. This proposal protects California consumers by ensuring that all licensed registered dental hygienists, applicants and staff use the same current terminology relative to dental hygiene education and practice; and that applicants understand the requirements and procedures for written and clinical examinations required for licensure, and adhere to the same minimum standards for infection control as other dental professionals.

C. Consistency and Compatibility with Existing State Regulations

After conducting a review of any regulations that would relate to or affect this area, the Committee has evaluated this regulatory proposal and it is not inconsistent or incompatible with existing State regulations.

FISCAL IMPACT ESTIMATES

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.

Local Mandate: None.

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

Business Impact: The Committee has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business:

The Committee 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 Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Committee has determined that the proposed regulations would not have a significant economic impact on small businesses because only dental hygiene applicants and licensees would be affected by these regulations.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/Businesses:

The Committee has determined that this regulatory proposal will not have a significant 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 Regulation:

The Committee has determined that this regulatory proposal will have the following benefits to health and welfare of California residents, worker safety and state’s environment:

This regulation will benefit the state’s environment and the health of California residents and workers by ensuring that dental hygienist applicants and licensees have clear and consistent definitions for terms used within statute. This regulation will benefit the public through timely investigation and enforcement actions

being delegated to the Executive Officer. This regulation will benefit applicants for dental hygiene licensure by clarifying the requirements and process for written and clinical examinations, and specifying an appeals process.

CONSIDERATION OF ALTERNATIVES

The Committee must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention 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 proposal described in this Notice, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Committee 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 at the hearing or prior to the hearing upon request from the Dental Hygiene Committee of California at 2005 Evergreen Street, Suite 1050, Sacramento, California 95815.

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 website listed below.

CONTACT PERSON

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

Name: Donna Kantner
 Address: 2005 Evergreen Street,
 Suite 1050
 Sacramento, CA 95815
 Telephone No.: (916) 263-1978
 Fax No.: (916) 263-2688
 E-mail Address: Donna.Kantner@dca.ca.gov

The backup contact person is:

Name: Lori Hubble, Executive Officer
 Address: 2005 Evergreen Street,
 Suite 1050
 Sacramento, CA 95815
 Telephone No.: (916) 263-1978
 Fax No.: (916) 263-2688
 E-mail Address: Lori.Hubble@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations in underline and strikeout can be accessed through our website at www.dhcc.ca.gov.

TITLE 16. STATE BOARD OF GUIDE DOGS FOR THE BLIND

NOTICE IS HEREBY GIVEN that the State Board of Guide Dogs for the Blind (hereinafter "Board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held on:

January 13, 2014 — 3:00 p.m.
State Capitol
Room 4203
Sacramento, CA 95814

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 at its office **on or before 5:00 p.m., January 13, 2014, or must be received by the Board at the hearing.** The Board, 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 pro-

posal 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 7208 of the Business and Professions Code, and to implement, interpret or make specific sections 7208 and 7211.9 of said Code, the Board is considering changes to Division 22 of Title 16 of the California Code of Regulations as follows:

A. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 7208 authorizes the Board to govern the admission of applicants for examination for licensure to instruct blind persons in the use of guide dogs or to engage in the business of training, selling, hiring, or being in the business of supplying guide dogs for the blind; govern the operation of schools which furnish guide dogs and train blind persons to use guide dogs.

Amend Section 2285.

Existing regulation provides guidelines for licensees providing instruction to persons who are blind or visually impaired. Such guidelines are general in nature and only relate to the release of personal information, equitable training standards for guide dog instructors and guide dog schools, and prohibition of intimidation or coercion of students.

- ▶ This proposed regulation would change the title of the Section from “Standards of Conduct” to “Ethical Standards of Practice for a Guide Dog Instructor or Guide Dog School.”
- ▶ The proposed language would
 - Clearly prescribe violation of such standards constituting grounds for disciplinary action.
 - Allow for release of personal information of a client, by a guide dog school or instructor, if local, state, or federal law requires such release.
 - Require written permission be obtained by a licensee before a client is photographed or tape-recorded.
 - Require that licensees abide by the Guide Dog Act, the Code of Regulations, and all other local, state, and federal laws.
 - Require guide dog instructors not use coercion, or violence, and abide by non-discrimination laws.

- Prohibit guide dog instructors from engaging in relationships or activities that would impair objective guide dog instruction.
- Require guide dog instructors collaborate with clients on training goals and objectives as well as decisions regarding continued guide dog usage.
- Require guide dog instructors inform client of nature, risks, and potential outcomes of guide dog usage.
- Require guide dog instructors provide information or materials regarding the training and use of guide dogs in large print, braille, or electronic format as deemed accessible by the client.
- Require a guide dog school obtain written permission from clients involved in fundraising, outreach, or fundraising activities and retain such permission in the client’s record.

B. POLICY STATEMENT OVERVIEW/ANTICIPATED BENEFITS OF PROPOSAL

In 2001, the Joint Legislative Sunset Review Committee (JLSRC) issued a recommendation that the Board define professional competence, negligence, or appropriate professional conduct for its licensees. In the Board’s 2012 report to the Senate Business, Professions, and Economic Development and Assembly Business, Professions, and Consumer Protection committees, it committed to completing a Practitioner Code of Ethics by 2014. The amended language for section 2285 meets the stated objective as prescribed by the legislature — a more clearly defined framework in which to practice guide dog instruction in a more ethical, transparent way with the objective in protecting consumers.

C. CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

After conducting a review for any regulations that would relate to or affect this area, the Board has evaluated this regulatory proposal and it is neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: There is no fiscal impact on public agencies unless non-compliance of the standards is established via the normal complaint process.

Nondiscretionary Costs/Savings to Local Agencies:
None.

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

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal 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. Because the Board relies on the input from the three (3) licensed schools, the feedback from the schools has not indicated any positive or negative impact on guide dog instructor jobs in the State.

Cost Impact on Representative Private Person or Business:

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

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses because the affected guide dog schools are non-profit organizations.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/Businesses

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs and existing businesses or the expansion of the businesses in the State of California.

Benefits of Regulation

The Board has determined that this regulatory proposal will benefit the licensed guide dog schools and guide dog instructors by providing clear guidelines for professional conduct while also protecting clients from unethical, unscrupulous and fraudulent business practices.

CONSIDERATION OF ALTERNATIVES

The Board 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, would be as effective as and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

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 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 at the hearing or prior to the hearing upon request from the State Board of Guide Dogs for the Blind at 1625 N. Market Blvd., Suite S 202, Sacramento, California 95834.

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 website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Antonette Sorrick,
Executive Officer
Address: 1625 N. Market Blvd.,
Suite S-202
Sacramento, CA 95834
Telephone No.: (916) 574-7825
Fax No.: (916) 574-7829
E-mail Address: Antonette.Sorrick@dca.ca.gov

Name: Rosemary Robinson,
Executive Assistant
Address: 1625 N. Market Blvd.,
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Sacramento, CA 95834
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Website Access:

Materials regarding this proposal can be found at www.guidedogboard.ca.gov.

GENERAL PUBLIC INTEREST

DEPARTMENT OF FISH AND WILDLIFE

PROPOSED RESEARCH ON FULLY PROTECTED SPECIES

Monitoring California Least Tern Nesting Colonies

The Department of Fish and Wildlife (“Department”) received a proposal on August 20, 2013, from Nathan Mudry in Fullerton, California, requesting authorization to take California Least Terns (*Sternula antillarum browni*; tern), for research purposes, consistent with the protection and recovery of the subspecies. The tern is a Fully Protected bird, and is also listed as Endangered under the California Endangered Species Act and Endangered under the federal Endangered Species Act.

Mr. Mudry is planning to conduct research on the tern in Los Angeles County, in accordance with methods approved by the Department and the U.S. Fish and Wildlife Service (Service; under a current Recovery Permit). The purpose of the research is to quantify nesting success and assess the populations that utilize nesting sites in Los Angeles County, including the Port of LA, in order to provide management guidance to the port, beach owners, and governmental agencies with a statutory responsibility to protect the species. The proposed research activities include monitoring reproductive out-

put of terns using binoculars and spotting scopes, and passive survey techniques such as transects, point counts, and area searches, and active survey techniques including entering active tern nesting areas to visually survey, mark, and monitor nests and determine age class of individuals. Tern carcasses and non-viable tern eggs found during research and nest monitoring activities will be salvaged and donated to a depository designated by the Department and the Service. There would be no attempt to capture individual live terns, unless specifically approved by the Department. No adverse effects on individual terns or tern populations are expected.

The Department intends to issue, under specified conditions, a Memorandum of Understanding (MOU) to authorize qualified professional wildlife researchers, with Mr. Mudry as the Principal Investigator, to carry out the proposed activities. The applicants are also required to have a valid federal recovery permit for the tern, and a scientific collecting permit (SCP) to take other terrestrial species in California.

Pursuant to California Fish and Game Code (FGC) Section 3511(a)(1), the Department may authorize take of Fully Protected Birds 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 is consistent with the requirements of FGC Section 3511 for take of Fully Protected birds, it would issue the authorization on or after December 30, 2013, for an initial and renewable term of three years. Contact: Nancy Frost, nancy.frost@wildlife.ca.gov, Phone 858-467-4208.

DEPARTMENT OF FISH AND WILDLIFE

PROPOSED RESEARCH ON A FULLY PROTECTED SPECIES

Research on the Salt-Marsh Harvest Mouse

The Department of Fish and Wildlife (Department) received a proposal on June 6, 2013 from Anastasia Ennis, San Francisco State University, San Francisco, California, requesting authorization to capture the salt-marsh harvest mouse (*Reithrodontomys raviventris*) (mouse) for research purposes consistent with the protection and recovery of the species. The mouse is a Fully Protected mammal and is also listed as Endangered under the California Endangered Species Act and Endangered under the federal Endangered Species Act.

Ms. Ennis is planning to conduct research on the mouse throughout its range, in accordance with methods approved by the Department and the U.S. Fish and Wildlife Service (Service, under a current Recovery

Permit). The purpose of the research is to characterize genetic variation in both subspecies of the mouse (*R. r. haelicoetes* and *R. r. raviventris*) and to identify correlations between genetic data and the presence of parasites. This information can be used by land managers as a starting point to estimate population sizes, plan for restoration of mouse habitat, and design dispersal corridors to connect key populations. The proposed research activities include collection of follicular tissue samples from plucked hair, fecal samples and muscle tissue from mice during live-trapping sessions, including during trapping sessions by other permitted mouse researchers. Tissue samples may also be taken from salvaged mouse carcasses when available, and from museum specimens. All salvaged mice will be donated to a scientific depository designated by the Department and the Service. No adverse effects on individual mice or mouse populations are expected.

The Department intends to issue, under specified conditions, a Memorandum of Understanding (MOU) to authorize Ms. Ennis to carry out the proposed activities. The applicant is also required to have a valid federal Recovery Permit for the mouse, and a Scientific Collecting Permit (SCP) to take other terrestrial mammal species in California.

Pursuant to California Fish and Game Code (FGC) Section 4700(a)(1), the Department may authorize take of Fully Protected mammal species after a 30 day notice has been provided to affected and interested parties through publication of this notice. If the Department determines that the proposed research is consistent with the requirements of FGC Section 4700 for take of Fully Protected mammals, it would issue the authorization on or after December 29, 2013, for an initial and renewable term of three years. Contact: Scott Osborn, Scott.Osborn@wildlife.ca.gov, (916) 324-3564.

**DEPARTMENT OF HEALTH
CARE SERVICES**

THE DEPARTMENT OF HEALTH CARE SERVICES PROPOSES TO EXEMPT DENTAL PEDIATRIC SURGERY CENTERS THAT PROVIDE SERVICES TO AT LEAST 95 PERCENT OF THEIR MEDI-CAL BENEFICIARIES UNDER THE AGE OF 21 FROM THE MEDI-CAL TEN PERCENT PROVIDER PAYMENT REDUCTION

This notice provides information of public interest about the California Department of Health Care Services' (DHCS') proposal to exempt dental pediatric surgery centers that provide services to at least 95 percent of their Medi-Cal beneficiaries under the age of 21

from the Medi-Cal ten percent provider payment reduction as enacted by Assembly Bill (AB) 97 (Statutes of 2011). This exemption will be effective for claims adjudicated on or after December 1, 2013. DHCS will periodically re-evaluate the dental pediatric surgery centers to confirm which dental pediatric surgery centers meet the 95 percent Medi-Cal children threshold required for the exemption. AB 97 added section 14105.192 to the Welfare and Institutions Code which requires DHCS to reduce provider payments up to 10 percent for various outpatient services, effective for dates of service on or after June 1, 2011. Paragraph (4) of subdivision (d) of section 14105.192 authorizes the Director of DHCS to adjust the payment reductions specified in section 14105.192 with respect to particular provider types, products, or services. The adjustments may be to zero, which would result in a total exemption from any payment reduction for the particular provider type, product, or service. The exemption is being made to ensure that Medi-Cal beneficiaries with severe dental disease under the age of 21 have access to care.

PUBLIC REVIEW AND COMMENTS

Written comments (or requests for copies of the statutes) may be submitted to: Andrew McCray, Chief, Medi-Cal Dental Services Division; Department of Health Care Services; MS 4708, P.O. Box 997413, Sacramento, CA 95899-7413.

DEPARTMENT OF PUBLIC HEALTH

TITLE: PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT (STATE PLAN) FOR FEDERAL FISCAL YEAR (FFY) 2014

ACTION: NOTICE OF HEARINGS FOR PROPOSED FUNDING

SUBJECT

The Centers for Disease Control and Prevention has made funds available to the California Department of Public Health (CDPH) for the development and implementation of programs and activities to decrease the morbidity and mortality that results from preventable disease and injury. The purpose of this hearing is to discuss and receive comments on the State's recommendations for the use of these funds during State Fiscal Year 2013-14 (FFY 2014).

PUBLIC HEARING PROCESS

Notice is hereby given that CDPH will hold a public hearing commencing at 10:00 a.m. on Monday, January

13, 2014 in Room 74.463 (Kings Room) 1616 Capitol Avenue, Sacramento, California, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. If you plan to attend the Public Hearing, please be sure to bring identification so you can be admitted into the building by the security guard. The Chronic Disease Control Branch, CDPH, 1616 Capitol Avenue, MS 7209, P.O Box 997377, Sacramento, CA, 95899-7377 must receive any written statements or arguments by 5:00 p.m. January 13, 2014 which is hereby designated as the close of the written comment period. It is requested, but not required, that written statements or arguments be submitted in triplicate.

CONTACT

Inquiries concerning the action described in this notice may be directed to Ms. Marcia Levy Rosenstein, Preventive Health and Health Services Block Grant Coordinator, at (916) 552-9900 at Marcia.Rosenstein@cdph.ca.gov or Anita Butler, Chief of the Administration and Policy Section, at Anita.Butler@cdph.ca.gov. In any such inquiries, please identify the action by using the Department Control letters "PHHSBG."

AVAILABILITY OF INFORMATION FOR REVIEW

The State Plan will be available for review at 1616 Capitol Avenue, Sacramento, California, from 8:00 a.m. to 5:00 p.m., November 29, 2013 through January 13, 2014 through January 29, 2013.

PROPOSITION 65

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (Proposition 65)

NOTICE OF INTENT TO LIST: TRICHLOROETHYLENE

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list the chemical trichloroethylene (TCE) as known to the State to cause reproductive tox-

icity under the Safe Drinking Water and Toxic Enforcement Act of 1986.¹ This action is being proposed under the authoritative bodies listing mechanism.²

Chemical (CAS No.)	Endpoints	Reference	Occurrence and Uses
Trichloroethylene (CAS# 79-01-6)	Male reproductive toxicity Developmental toxicity	U.S. Environmental Protection Agency (U.S. EPA, 2011a,b)	Used mainly in vapor degreasing of metal parts, also used as a solvent in the textile industry and is found in consumer products such as paint removers and adhesives.

Background on listing via the authoritative bodies mechanism: A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)³).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(h)).

The U.S. Environmental Protection Agency (U.S. EPA) is one of several institutions designated as authoritative for the identification of chemicals as causing reproductive toxicity (Section 25306(l)).

OEHHA is the lead agency for Proposition 65 implementation. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

OEHHA's determination: *Trichloroethylene* meets the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on the findings of U.S. EPA (U.S. EPA, 2011a), as outlined below.

¹ Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 *et seq.*

² See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25306.

³ All referenced sections are from Title 27 of the Cal. Code of Regulations.

Formal identification and sufficiency of evidence for trichloroethylene: In 2011, U.S. EPA published a report on TCE, entitled *Toxicological Review of Trichloroethylene (CAS No. 79-01-6)* (U.S. EPA, 2011a). This report satisfies the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on U.S. EPA's discussion of data and conclusions in the *Toxicological Review* that TCE causes reproductive toxicity. U.S. EPA also concluded that TCE causes reproductive toxicity in its entry in the Integrated Risk Information System (IRIS) for TCE (U.S. EPA, 2011b). That entry cites the *Toxicological Review* of TCE as providing the supporting documentation (U.S. EPA, 2011a).

The conclusions in the U.S. EPA (2011a) *Toxicological Review* document identify TCE as causing male reproductive and developmental toxicity in laboratory animals, and satisfy the formal identification criteria in the Proposition 65 regulations.

With regard to male reproductive toxicity, U.S. EPA stated that for TCE:

- “Together, the human and laboratory animal data support the conclusion that TCE exposure poses a potential hazard to the male reproductive system” (Major Conclusions in the Characterization of Hazard and Dose Response, page 6–9).
- “[T]here is strong and compelling evidence for adverse effects of TCE exposure on male reproductive system and function” (Discussion/Synthesis of Noncancer Reproductive Toxicity Findings, page 4–487).

In discussing the evidence on male reproductive toxicity for TCE, U.S. EPA states:

“The adverse effects that have been observed in both male humans and male animal models include altered sperm count, morphology, or motility (Kumar et al., 2001b; Veeramachaneni et al., 2001; Kumar et al., 2000a; Kumar et al., 2000b; Chia et al., 1996; Rasmussen et al., 1988; George et al., 1985; Land et al., 1981); decreased libido or copulatory behavior (Veeramachaneni et al., 2001; George et al., 1986; Zenick et al., 1984; Saihan et al., 1978; El Ghawabi et al., 1973; Bardodej and Vyskocil, 1956); alterations in serum hormone levels (Veeramachaneni et al., 2001; Kumar et al., 2000a; Goh et al., 1998; Chia et al., 1997); and reduced fertility (George et al., 1986). However, other studies in humans did not see evidence of altered sperm count or morphology (Rasmussen et al., 1988) or reduced fertility (Forkert et al., 2003; Sallmen et al., 1998), and some animal studies also did not identify altered sperm measures (Xu et al., 2004; Cosby

and Dukelow, 1992; George et al., 1986; Zenick et al., 1984). Additional adverse effects observed in animals include histopathological lesions of the testes (Kumar et al., 2001b; Kumar et al., 2000b; George et al., 1986) or epididymides (Kan et al., 2007; Forkert et al., 2002) and altered in vitro spermocyte binding and/or in vivo fertilization for TCE and/or its metabolites (DuTeaux et al., 2004a; Xu et al., 2004) (page 4–488, citations in U.S. EPA Toxicological Review (2011 a)).

“In spite of the preponderance of studies demonstrating effects on sperm parameters, there is an absence of overwhelming evidence in the database of adverse effects of TCE on overall fertility in the rodent studies. That is not surprising, however, given the redundancy and efficiency of rodent reproductive capabilities. Nevertheless, the continuous breeding reproductive toxicity study in rats (George et al., 1986) did demonstrate a trend towards reproductive compromise (i.e., a progressive decrease in the number of breeding pairs producing third, fourth, and fifth litters).” (page 4–490, citations in U.S. EPA Toxicological Review (2011a)).”

Regarding developmental toxicity, the U.S. EPA Toxicological Review states that:

- “[B]ased on weakly suggestive epidemiologic data and fairly consistent laboratory animal data, it can be concluded that TCE exposure poses a potential hazard for prenatal losses and decreased growth or birth weight of offspring.” (Major Conclusions in the Characterization of Hazard and Dose Response, page 6–10)
- “[B]ased on weakly suggestive, but overall consistent, epidemiologic data, in combination with evidence from experimental animal and mechanistic studies, it can be concluded that TCE exposure poses a potential hazard for congenital malformations, including cardiac defects, in offspring.” (Major Conclusions in the Characterization of Hazard and Dose Response, page 6–11)

Scientific evidence of developmental toxicity reviewed by the authoritative body in support of these conclusions includes a number of human and animal studies. With regard to prenatal loss and effects on growth, the U.S. EPA Toxicological Review (2011a) noted that some occupational and environmental epidemiological studies reported associations between parental exposure to TCE and spontaneous abortion or perinatal death, and decreased birth weight or SGA [small for gestational age], although other studies reported mixed or null findings, and that multiple well-

conducted studies in rats and mice show analogous effects of TCE exposure; i.e., pre- or postimplantation losses, increased resorptions, perinatal death, and decreased birth weight. On that basis, U.S. EPA concluded that TCE exposure poses a potential hazard for prenatal losses and decreased growth or birth weight of offspring, based on weakly suggestive epidemiologic data and fairly consistent laboratory animal data.

With regard to malformations, the U.S. EPA Toxicological Review (2011a) noted that epidemiological studies, while individually limited, as a whole show relatively consistent elevations, some of which were statistically significant, in the incidence of cardiac defects in TCE-exposed populations compared to reference groups. In laboratory animal models, avian studies were the first to identify adverse effects of TCE exposure on cardiac development, and the initial findings have been confirmed multiple times. Additionally, administration of TCE and its metabolites, TCA and DCA, in maternal drinking water during gestation has been reported to induce cardiac malformations in rat fetuses.

The studies cited by U.S. EPA in support of these conclusions were reviewed by OEHHA with regard to the sufficiency of evidence criteria in regulation (Section 25306(g)). The criteria for listing TCE as known to cause reproductive toxicity by the authoritative bodies mechanism have been met.

Request for comments⁴: OEHHA is requesting comments as to whether trichloroethylene meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. In order to be considered, **OEHHA must receive comments by 5:00 p.m. on Monday, January 13, 2013.** We encourage you to submit comments via e-mail, rather than in paper form. Comments transmitted by e-mail should be addressed to P65Public.Comments@oehha.ca.gov with "NOIL-TCE" in the subject line. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address: Ms. Cynthia Oshita
Office of Environmental
Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, CA 95812-4010

Fax: (916) 323-2265

Street Address: 1001 I Street
Sacramento, CA 95814

Comments received during the public comment period will be posted on the OEHHA web site after the close of the comment period.

If you have any questions, please contact Ms. Oshita at cynthia.oshita@oehha.ca.gov or at (916) 445-6900.

References

U.S. EPA (U.S. Environmental Protection Agency) (2011a). Toxicological Review of Trichloroethylene (CAS No. 79-0106); In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-09/011F U.S. EPA, Washington D.C., September 2011. Available online at: <http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>.

U.S. EPA (U.S. Environmental Protection Agency) (2011 b). Trichloroethylene (CASRN 79-01-6). Integrated Risk Information System. Available online at: <http://www.epa.gov/iris/subst/0199.htm>.

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# 2013-1008-01
BOARD FOR PROFESSIONAL ENGINEERS,
LAND SURVEYORS AND GEOLOGISTS
Seal, Signature, and Address Change

In October of 2009, the Board for Professional Engineers, Land Surveyors, and Geologists assumed jurisdiction to regulate the practices of geology and geophysics from the Board for Geologists and Geophysicists. The Board for Professional Engineers, Land Surveyors, and Geologists amended sections 411, 412, 3008, and 3009 of title 16 of the California Code of Regulations largely to establish uniformity in the regulations governing those professions under its jurisdiction.

Title 16
California Code of Regulations
AMEND: 411, 412, 3008, 3009
Filed 11/18/2013
Effective 01/01/2014
Agency Contact: Jeff Alameida (916) 263-2269

⁴ Note: OEHHA requested information relevant to the possible listing of trichloroethylene in a notice published in the *California Regulatory Notice Register* on March 15, 2013 (Register 2013, Vol. No. 11-Z). OEHHA received and has responded to those comments in a separate document.

File# 2013-1004-02
BOARD OF ACCOUNTANCY
 Military Inactive Status

This regulatory action by the California Board of Accountancy amends Title 16 by adopting new sections to implement newly enacted Business and Professions Code section 5070.2, which creates a military inactive status of licensure for accountants who are active duty in the California National Guard or the United States Armed Forces.

Title 16
 California Code of Regulations
 ADOPT: 16, 16.1, 16.2
 Filed 11/13/2013
 Effective 01/01/2014
 Agency Contact: Matthew Stanley (916) 561-1792

File# 2013-1028-01
DEPARTMENT OF BUSINESS OVERSIGHT
 Parity Regulations — Derivative Transactions

This regulatory action requires subject institutions to comply with 12 C.F.R. Part 32.9, subsections (a) and (b) as if the subject institution were a California state chartered bank. This action is exempt from Government Code section 11343.4 and Articles 5 and 6 of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code.

Title 10
 California Code of Regulations
 ADOPT: 10.190500, 10.190501
 Filed 11/19/2013
 Effective 11/19/2013
 Agency Contact: Manuela Rumsey (916) 322-5983

File# 2013-1015-02
DEPARTMENT OF FISH AND WILDLIFE
 Fees for Lake and Streambed Alteration

This regulatory action amends the fees for lake and streambed alteration.

Title 14
 California Code of Regulations
 AMEND: 699.5
 Filed 11/19/2013
 Effective 01/01/2014
 Agency Contact: Mike Randall (916) 653-4678

File# 2013-1104-02
DEPARTMENT OF FOOD AND AGRICULTURE
 Oak Mortality Disease Control

This emergency regulatory action will establish "Gaultheria procumbens" (wintergreen, Eastern teaberry and boxberry) as an associated article under the

articles and commodities covered by Section 3700. The effect of this amendment will provide authority to the State to regulate the movement of this new "associated article (nursery stock)" to prevent artificial spread of oak mortality disease to non-infested areas. These plants are being added to the list of plants whose movements are regulated as hosts or potential carriers that may transfer the disease from an infested area.

Title 3
 California Code of Regulations
 AMEND: 3700(c)
 Filed 11/13/2013
 Effective 11/27/2013
 Agency Contact: Stephen S. Brown (916) 654-1017

File# 2013-1112-02
DEPARTMENT OF INSURANCE
 Mental Health Parity

The Department of Insurance (Department) submitted this emergency readoption action to keep in effect the regulations adopted in OAL File Nos. 2013-0228-04E and 2013-0829-01EE. In those actions, the Department adopted in title 10 of the California Code of Regulations four sections pertaining to treatment of autism under a new article pertaining to mental health parity. The regulations pertain to insurer coverage under disability or health insurance policies, as further specified under Insurance Code sections 10144.5 and 10144.51, of therapies for individuals diagnosed with pervasive developmental disorder or autism. The regulations prohibit specified conditions or limitations on coverage of these therapies when determined to be medically necessary to ensure compliance with the Mental Health Parity Act.

Title 10
 California Code of Regulations
 ADOPT: 2562.1, 2562.2, 2562.3, 2562.4
 Filed 11/20/2013
 Effective 12/09/2013
 Agency Contact: George Teekell (415) 538-4390

File# 2013-1015-10
DEPARTMENT OF INSURANCE
 Commissioner's Review of Unlawful Health Insurance Terminations

This rulemaking action provides a procedural mechanism for the Department to review the lawfulness of health insurance terminations following a consumer's request for review, a proper complaint and the insurer's request for a hearing. These regulations also provide specificity as to the type of evidence that insurers may provide in order to demonstrate that a termination was lawful.

Title 10
California Code of Regulations
ADOPT: 2274.50, 2274.51, 2274.52, 2274.53,
2274.54, 2274.55, 2274.56, 2274.57, 2274.58,
2274.59, 2274.60
Filed 11/20/2013
Effective 01/01/2014
Agency Contact: Eugene Kalinsky (415)538-4113

File# 2013-1015-05
DEPARTMENT OF PARKS AND RECREATION
Grants and Cooperative Agreements Program

This regulatory action by the Department of Parks and Recreation amends sections of Title 14, to make minor revisions to the existing Grants and Cooperative Agreements Program. The changes alter the funding distribution for the development, planning, and acquisition subcategories of "Off Highway" recreation areas.

Title 14
California Code of Regulations
AMEND: 4970.00, 4970.10.2, 4970.10.3,
4970.10.4, 4970.15.1, 4970.15.2
Filed 11/14/2013
Effective 01/01/2014
Agency Contact: Sixto Fernandez (916)324-1572

File# 2013-1015-07
FISH AND GAME COMMISSION
Abalone

This regulatory action amends section 29.15 that deals with the take of abalone. No abalone may be taken in the Fort Ross area. Abalone may now only be taken from 8:00 a.m., instead of one-half hour before sunrise, to one-half hour after sunset. The bag limit was changed from the prior limit of 24 abalone to 18 abalone during the calendar year, except not more than 9 abalone of the yearly trip may be taken south of the boundary between Sonoma and Mendocino counties to the line drawn due west magnetic from the center of the mouth of San Francisco Bay. No other changes to the take of abalone were made.

Title 14
California Code of Regulations
AMEND: 29.15
Filed 11/20/2013
Effective 01/01/2014
Agency Contact: Sherrie Fonbuena (916)654-9866

File# 2013-1011-01
FISH AND GAME COMMISSION
Meeting Procedures

In this regulatory action, the Fish and Game Commission is adding section 665 to title 14, division 1, subdivision 3, chapter 2, of the California Code of Regulation.

This provision addresses meeting procedures. It designates the presiding commissioner as the person who will set the time allotted for each speaker wishing to address an agenda item.

Title 14
California Code of Regulations
ADOPT: 665
Filed 11/18/2013
Effective 01/01/2014
Agency Contact: Sherrie Fonbuena (916)654-9866

File# 2013-1104-04
MANAGED RISK MEDICAL INSURANCE BOARD
AIM Implement MAGI & End of Month Disenrollment

This emergency regulatory action by the Managed Risk Medical Insurance Board amends sections of Title 10, modifying the eligibility requirements for the Access for Infants and Mothers (AIM) program and the end of month disenrollment from the AIM program. These changes are effective January 1, 2014.

Title 10
California Code of Regulations
AMEND: 2699.200, 2699.207
Filed 11/13/2013
Effective 11/13/2013
Agency Contact: JoAnne French (916)327-7978

File# 2013-1104-05
MANAGED RISK MEDICAL INSURANCE BOARD
Continue MRMIP 2013 Subscriber Subsidy

Section 25 of Assembly Bill (AB) 82 (Stats. 2013, ch. 23) amended subdivision (c) of Insurance Code section 12737 to give the Managed Risk Medical Insurance Board (Board) ongoing authority beyond 2013 to subsidize subscriber premiums to as low as 100% of the standard average individual rates for comparable coverage. The Board by this emergency filing amended section 2698.401 of title 10 of the California Code of Regulations to implement this change and to provide that beginning January 1, 2014 the Board shall calculate an estimate of the standard average individual rate for program benefits for each risk category and for covering a subscriber in each risk category. Pursuant to section 77 of AB 82, this filing is deemed an emergency by the Legislature and exempt from review by the Office of Administrative Law.

Title 10
California Code of Regulations
AMEND: 2698.401
Filed 11/13/2013
Effective 11/13/2013
Agency Contact: JoAnne French (916)327-7978

File# 2013-1010-01
 SECRETARY OF STATE
 Business Entity Names

The Secretary of State amended ten sections and adopted three sections under title 2 of the California Code of Regulations that concern the availability of business entity names for corporations, foreign corporations, limited liability companies, foreign limited liability companies, limited partnerships and foreign limited partnerships. The amendments are intended to reflect new statutory standards for limited liability company names enacted in the California Revised Uniform Limited Liability Company Act (S.B. 323; Stats. 2012, c. 419; operative Jan. 1, 2014). The amendments are also intended to clear up ambiguities and inconsistencies identified in the first four years of administering the business entity names regulations since their initial adoption in 2009.

Title 2
 California Code of Regulations
 ADOPT: 21001.1, 21001.2, 21001.3
 AMEND: 21000, 21001, 21002, 21003, 21004, 21005, 21006, 21007 (re-numbered to 21004.5), 21008, 21009 (re-numbered to 21005.5)
 Filed 11/19/2013
 Effective 01/01/2014
 Agency Contact: Susan Lapsley (916) 651-7837

**CCR CHANGES FILED
 WITH THE SECRETARY OF STATE
 WITHIN June 19, 2013 TO
 November 20, 2013**

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 1

10/29/13 ADOPT: 2000, 2001, 2002, 2003, 2004

Title 2

11/19/13 ADOPT: 21001.1, 21001.2, 21001.3
 AMEND: 21000, 21001, 21002, 21003, 21004, 21005, 21006, 21007 (re-numbered to 21004.5), 21008, 21009 (re-numbered to 21005.5)
 11/04/13 AMEND: 1859.2, 1859.71, 1859.71.6, 1859.74.5, 1859.77.4, 1859.82, 1859.83
 10/30/13 AMEND: 1859.76

10/25/13 ADOPT: 579.3, 579.21, 579.22, 579.25
 AMEND: 579.2
 10/03/13 AMEND: 18521.5
 10/03/13 ADOPT: 18421.5
 10/03/13 AMEND: 18239
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 10/14/13 AMEND: 3435(b)
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