

**STATE OF CALIFORNIA
DEPARTMENT OF INSURANCE
45 Fremont Street
San Francisco, California 94105**

**NOTICE OF PROPOSED EMERGENCY ACTION
PURSUANT TO INSURANCE CODE SECTION 10112.27 AND
GOVERNMENT CODE SECTION 11346.1**

Date: May 24, 2013

REGULATION FILE: ER-2012-00001

ESSENTIAL HEALTH BENEFITS REGULATION

**OPPORTUNITY FOR INTERESTED PARTIES TO SUBMIT COMMENTS TO THE
OFFICE OF ADMINISTRATIVE LAW**

Paragraph (a)(2) of Government Code section 11346.1 requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

EXPRESS FINDING OF EMERGENCY

AUTHORITY AND REFERENCE

The proposed regulations will implement, interpret, and make specific the provisions of Insurance Code section 10112.27. Subdivision (o) of Insurance Code section 10112.27 provides authority for this rulemaking.

**INFORMATIVE DIGEST; DESCRIPTION OF THE PROBLEM AND THE NECESSITY
FOR THE REGULATION**

Summary of Existing Law

Senate Bill 951 (Stats. 2012, ch. 866) enacted California's essential health benefit requirements 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. These proposed regulations effectuate section 10112.27 through

implementing the statute consistent with PPACA and subsequent federal implementing regulations on essential health benefits.

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

¹ Federal law speaks in terms of a “health insurance issuer,” which is “an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed 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.)

2) *A Specific Requirement to Provide the Levels of Coverage Is Codified at Subdivision (d) of Insurance Code Section 10112.3*

The PPACA levels of coverage requirement, an element of the essential health benefits package, was enacted into Insurance Code section 10112.3 by the California Patient Protection and Affordable Care Act (Stats. 2010, ch. 655 (A.B. 1602)). 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”

3) *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 would serve 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-benchmark 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 selected FEDVIP as the state’s supplemental benefits plan for pediatric vision benefits. (Ins. Code § 10112.27(a)(4).) Section 10112.27 selected 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 treatment limitations on essential health benefits coverage shall be no greater than the treatment limitations imposed by the base-benchmark plan, FEDVIP, and CHIP.

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 coverage 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 base-benchmark, CHIP, and FEDVIP 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.

4) 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. Under subsection (a)(1), the annual out-of-pocket maximum for an individual or group plan in 2014 may not exceed the annual out-of-pocket limits for high deductible health plans published by the IRS pursuant to the Internal Revenue Code (\$6,350 for self-only coverage and \$12,700 for other than self-only, or family, coverage, in 2014). Subsection (a)(2) provides for adjustment of the annual limitation on cost sharing for years after 2014. Subsection (b)(1) provides for the statutory annual limitations on small group market deductibles in 2014 (\$2,000 for self-only coverage and \$4,000 for other than self-only, or family, coverage, in 2014). Subsection (b)(2) provides for adjustment of the annual deductible limits for years after 2014. Subsection (b)(3) provides for an exception from the small group deductible limit if a plan may not reasonably reach the actuarial value of a given level of coverage without exceeding the limit. Subsection (c) provides that cost sharing for benefits obtained out-of-network does not count towards the annual limitations on cost sharing and small group deductibles. Subsection (g)(1) provides that emergency department services must be covered without imposing a pre-authorization requirement or “any limitation on coverage where the provider of services is out of network that is more restrictive than the requirements or limitations that apply to emergency department services received in network[.]” Subsection (g)(2) applies

the limits on cost sharing in 45 C.F.R. section 147.138(b)(3) to out-of-network emergency department services.

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 employer contributions to health savings accounts and amounts made available under health reimbursement arrangements may 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 (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 catastrophic 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.

5) 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 take over the state's health insurance policy review functions.

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, 156.130, 156.135, 156.140, 156.150, and 156.155 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 regulations is to implement Insurance Code section 10112.27, which itself implements PPACA's essential health benefits requirement through selecting California's benchmark plan and making other choices within the framework described in the federal *Essential Health Benefits Bulletin*. Insurance Code section 10112.27 was enacted before the federal essential health benefits regulations were proposed. Consequently, the statute did not anticipate and resolve every issue concerning essential health benefits. For this reason section 10112.27 contains a caveat at subdivision (j) stating that it shall not be implemented in a manner that conflicts with PPACA.

The proposed regulations are urgently needed because the Department is responsible for enforcing the essential health benefits package in health insurance policy forms that are presently being filed for the Department's review and approval prior to the full implementation of PPACA in 2014. Because the changes to health insurance law brought about by national health reform are so fundamental and extensive, insurers wishing to participate in the individual and small group health insurance markets will have to file new policy forms with the Department for review and approval this year. Prior to this year, the entire body of governing federal law was not in place, as exemplified by the release of the final federal essential health benefits regulations only in February. The health insurance industry and regulatory agencies across the entire country are pressed for time in preparing and reviewing health insurance products for market in 2014, which is largely driven by federal timelines and the 2014 debut of the majority of PPACA's market reforms.

The Department requested submission of individual and small group policy forms and rates by June 1, 2013 to allow enough time for its attorneys and actuaries to review 2014 health insurance product filings for compliance with the law prior to open enrollment in October. Health insurers wishing to market their products during open enrollment require the guidance provided in these

proposed regulations to comply with the essential health benefits requirements and navigate the policy form submission and review process, which has been significantly altered by the essential health benefits requirements. These proposed regulations will promote transparency in health insurance regulation through clarifying the requirements for filing and legal compliance. The proposed regulations will also facilitate expeditious review of health insurance policy forms for compliance with the essential health benefits requirements so that California's health insurance market is open for business prior to 2014.

Although Insurance Code section 10112.27 is a comprehensive statute that settles many policy questions concerning California's essential health benefits coverage requirement, many critical issues remain unresolved and thus require further specification. For example, the statute does not specifically address annual limitations on cost sharing and small group deductibles and the levels of coverage components of the essential health benefits package. These components of the essential health benefits package are, like the essential health benefits coverage requirement, new to health insurance regulation. All three components of the essential health benefits package are intrinsic elements of a health insurance policy, which sets forth the covered benefits and cost sharing associated with those benefits.

Prior to PPACA and the essential health benefits implementing regulations, health insurers were not constrained in terms of cost sharing provisions or levels of coverage. These two components of the essential health benefits package both tie back to, and are inextricably linked with, the third component, the requirement for coverage of essential health benefits; all three components are enforced in policy form review. In order to avoid conflicts between state and federal law consistent with section 10112.27(j), all three components must be considered together. Consequently, this proposed regulation encompasses all three elements of the essential health benefits package. This is necessary both to avoid conflict with federal law, and to assure regulatory consistency. The Department cannot approve health insurance products for sale in 2014 without verifying that the policies provide the complete essential health benefits package.

While the basic rule that health insurers may only provide the levels of coverage in PPACA has been enacted into state law, at subdivision (d) of Insurance Code section 10112.3, the details of this rule with respect to actuarial value, the standards applicable to verification of actuarial value, and the process by which the rule will be enforced in policy form review is not addressed in state law. Cost sharing for essential health benefits determines actuarial value, which is a measure of the generosity of the coverage. Actuarial value is now an integral component of the coverage provided by a health insurance policy, and was standardized by PPACA at the metal levels of coverage so consumers could more easily compare different health insurance products.

The federal essential health benefits regulation adopted detailed requirements for the calculation of actuarial value and the demonstration of compliance with the levels of coverage requirement that must be enforced in California. Significantly, if the health plan's design is incompatible with the federal actuarial value calculator, subdivision (b) of section 156.135 requires insurers to submit an actuarial certification to the state agency responsible for policy review of the actuarial value calculated using one of the two permissible methods presented in the rule. Proposed section 2594.7 implements a procedure through which these actuarial certifications would be submitted to the Department and standards for compliance review, and is necessary for

enforcement of this federal requirement. The only possible means through which a process for verification of actuarial value of health insurance products may be implemented in California in time for the review of 2014 health insurance policy forms is if proposed section 2594.7 is adopted.

The other component of the essential health benefits package, PPACA's annual limitation on cost sharing and small group deductibles, is not presently specifically required under state law. If the Department is to implement section 10112.27 consistent with PPACA and enforce these new requirements in 2014 health insurance policies, they must be adopted through the rulemaking process. These proposed regulations will promote and protect the interests of California's consumers, many of whom will be purchasing health insurance for the first time in the fall, and who expect to be protected by all of PPACA's reforms. Without these proposed regulations, the Department may have difficulty substantially enforcing the complete essential health benefits package in 2014 health insurance filings, possibly resulting in federal involvement in the state form review process.

Many details of the essential health benefits coverage mandate require additional explication as well. For example, the choice of the Kaiser small group plan as California's base-benchmark plan and decision to incorporate Health and Safety Code provisions as essential health benefits means that insurers are subject to additional laws with which they are unfamiliar, including basic health care services and other coverage mandates that were previously only applicable to health care service plans regulated by the Department of Managed Health Care. The proposed regulation clarifies the extent to which insurers must comply with the Health and Safety Code. Additionally, the evidence of coverage for the base-benchmark plan refers to durable medical equipment and soft goods formularies that are not publicly available. The regulation therefore lists all of the equipment and supplies that must be covered as essential health benefits. The regulation also specifies, pursuant to section 10112.27(a)(2)(A)(v), the benefits that are essential health benefits because they were covered by the base-benchmark plan independently of applicable mandates in the Knox-Keene Act.

The proposed regulations incorporate details of the federal regulations related to standards for coverage of essential health benefits that are not included in state law. The federal regulations included details of prescription drug coverage that must be enforced by states. The proposed regulations incorporate this new rule and address the procedure for enforcement. State law also does not specify the age limit of eligibility for pediatric services. The proposed regulations adopt the age provided by HHS, nineteen, in the preamble to the proposed federal rule on essential health benefits (77 Fed. Reg. 70,644, 70,649 (November 26, 2012).) The proposed regulations also include an explicit prohibition on discrimination in benefit design modeled after federal law. This provision prohibits insurers from designing their products to inhibit individuals with health conditions from enrolling, and 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 their health.

In summary, section 10112.27 requires further clarification and specification in order to fully implement the essential health benefits package in California. Because section 10112.27 was enacted prior to the release of the federal essential health benefits rule, much of this clarification

involves incorporating the details of the federal regulation on essential health benefits into the framework provided by section 10112.27. Due to the compressed timeline involved in implementing the extensive changes to the health insurance market wrought by PPACA, section 10112.27 authorized the adoption of emergency regulations to implement the statute consistent with PPACA. These proposed emergency regulations interpret and implement section 10112.27 through incorporating federal essential health benefits law into state law, clarifying the essential health benefits coverage requirement, and providing procedures for enforcement through the policy form review process. Taken together, these proposed regulations will promote public health through ensuring that comprehensive health insurance policies providing all of PPACA's consumer protections are available to consumers beginning this fall.

Effect of Proposed Action

As a result of the proposed action, health insurance policies sold in California for the 2014 coverage year will be required by state law to provide the complete essential health benefits package. The proposed regulations implement, interpret, and make specific the requirements for coverage of essential health benefits, implement PPACA's annual limitations on cost sharing and small group deductibles and levels of coverage requirements, and establish the process through which insurers will submit health insurance policies containing verification of actuarial value to the Department for review of policy form compliance with the essential health benefits package. The proposed regulations align California law with federal law and ensure that the Department has the ability to substantially enforce PPACA's essential health benefits package in health insurance policy form filings that will be reviewed this summer.

Existing State Regulations

The proposed regulations are not inconsistent or incompatible with existing state regulations.

Incorporation by Reference

Proposed section 2594.7 incorporates qualification standards from the following publication by reference: *Qualification Standards for Actuaries Issuing Statements of Actuarial Opinion in the United States* (American Academy of Actuaries, Jan. 1, 2008), available online at http://www.actuary.org/files/qualification_standards.pdf (last accessed May 15, 2013).

MANDATES 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 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. The proposed regulations do not impose other nondiscretionary cost or savings on local agencies, and result in no cost or savings in federal funding to the State.

These proposed regulations will not impose additional costs on the Department of Insurance beyond those imposed by section 10112.27 of the Insurance Code.

DESCRIPTION OF SPECIFIC FACTS DEMONSTRATING THE EXISTENCE OF AN EMERGENCY AND THE NEED FOR IMMEDIATE ACTION; DESCRIPTION OF THE JUSTIFICATION FOR ADOPTION OF THE REGULATION AS AN EMERGENCY REGULATION

Subdivision (o) of Insurance Code section 10112.27 explicitly provides the Department with emergency rulemaking authority and deems the adoption of implementing emergency regulations “an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.” Subdivision (j) of Insurance Code section 10112.27 directs that implementation of the statute shall not conflict with PPACA. The compressed timeline for state implementation of PPACA and its implementing regulations foreclosed the possibility that these regulations could have been adopted through the nonemergency rulemaking process.

The adoption of these proposed rules is an emergency necessitating immediate action because of the short time frame in which the review of health insurance policy forms for legal compliance may take place prior to the full implementation of PPACA in 2014. Due to the implementation schedule dictated by the federal government, complete law governing essential health benefits was not available until February of this year. Because section 10112.27 was enacted in September 2012, two months before the proposed federal rule on essential health benefits was released, and five months before it became final, the statute did not anticipate every element of those rules that would require implementation in California. Section 10112.27 granted the Department emergency rulemaking power precisely because it was expected the Department would be implementing the statute in light of federal law on essential health benefits with little or no time to spare before 2014 policy review begins. Moreover, the statute requires that it be implemented consistent with PPACA, which is one of the principal purposes of the proposed regulations.

Because the changes to health insurance regulation created by federal health reform are so fundamental and extensive, health insurers planning to participate in the individual and small group markets will be submitting new policy forms to the Department within the next few weeks for review and approval so they may be marketed this fall during open enrollment for 2014. Over the last six years, the Department received an average of 537 health insurance filings each year, 60% of which were individual and small group filings. Filings generally contain multiple policy forms, on average between two and three policy forms per filing. The Department therefore expects to receive approximately 800 individual and small group health insurance policy forms for review this year. Moreover, filings are more complex than they have been in the past because of all the new law applicable to health insurance. For example, the Department is now also responsible for reviewing summaries of benefits and coverage (a uniform federal disclosure form) for each level of coverage for every individual and small group health insurance

product an insurer intends to sell. (Stats. 2013, ch. 1, § 8 (A.B.x1-2) (amending Ins. Code § 10603).) The levels of coverage requirement, which necessitates detailed review of cost sharing provisions, also makes policy review more complex and time-consuming.

The review period will be compressed this year because of the time constraints imposed by the federal implementation schedule. Essentially, the Department's attorneys and actuaries will have a maximum period of three to four months to review the majority of the estimated 800 health insurance policy forms that will be filed for compliance with all applicable laws and regulations, including a substantial body of new law. This time constraint is unprecedented; emergency regulations clarifying the essential health benefits requirements are therefore critically needed and will promote transparency in the policy review process during this period of transition. Policy form review is a painstaking and time-consuming process that can extend for many months depending on the amount of negotiation that is necessary to reach agreement on acceptable policy language. These proposed regulations will assist insurers in developing compliant policy forms and will facilitate their timely review, and are necessary for the proper functioning of the state's post-PPACA health insurance market.

Without these proposed regulations, the insurance industry will be forced to file health insurance policy forms with the Department in the absence of urgently needed guidance, and there will be no established standards in state law for establishing compliance with the essential health benefits package beyond the framework provided in sections 10112.27 and 10112.3. All three components of the essential health benefits package are new to health insurance regulation: essential health benefits coverage, limitations on cost sharing and small group deductibles, and levels of coverage. The Department receives inquiries concerning essential health benefits-related filing issues on a daily basis from insurers preparing health insurance policies. A particular topic of insurer confusion concerns how the requirement to provide the levels of coverage affects policy forms, which is addressed by proposed section 2594.7 of this rulemaking. Thus it is critically necessary, especially given the limited time available, that requirements applicable to each of these integral components of a health insurance policy be adopted through the emergency rulemaking process.

Due to the levels of coverage requirement in section 1302(d) of PPACA and section 10112.3(d) of the Insurance Code, health insurers may no longer seek approval of policy forms containing ranges of dollar values in variable brackets for benefits subject to cost sharing. Variable brackets indicate that the policy may be issued with any dollar value within the range of dollar values contained in the bracket. Beginning in 2014 all benefits subject to cost sharing, as well as annual out-of-pocket maximums and deductibles, must be specified for each level of coverage, or plan, because they affect the actuarial value, and in turn, the level of coverage provided by the plan. Because the Department is responsible for verifying levels of coverage, it is necessary to notify insurers of this change and the accompanying changes to established filing requirements in regulation. (See Article 1 of Subchapter 2 of Chapter 5 of Title 10 of the California Code of Regulations.) Proposed section 2594.7 requires that the statement of variables submitted with the policy form pursuant to 10 C.C.R. section 2213 contain specific values for all benefits subject to cost sharing so the Department may verify that insurers are complying with section 10112.3(d), as well as many of the other provisions of section 10112.3 that depend on level of coverage determinations.

Proposed section 2594.7 implements other filing requirements for demonstrating actuarial value that effectuate sections 10112.27 and 10112.3 of the Insurance Code, and that incorporate the enforcement mechanism in the federal rule at 45 C.F.R. section 156.135. As it stands now, the requirement for insurers to submit an actuarial certification of the method used to arrive at actuarial value for plan designs that are incompatible with the federal actuarial value calculator, or unique plan designs, is not codified in state law. A significant proportion of individual and small group policies are expected to be unique plan designs because the standardized benefit plan designs adopted by the California Health Benefit Exchange, which must be offered by all insurers participating in the individual and small group markets in the state regardless of Exchange participation, Ins. Code § 10112.3(e), are unique plan designs. Therefore, not having an established procedure in place for insurer submission of actuarial certifications and standards for review of unique plan designs for actuarial value will negatively affect a significant proportion of 2014 filings.

Proposed section 2594.7 incorporates the federal standards for demonstrating the actuarial value of unique plan designs and provides procedures for the enforcement of section 10112.3(d) through the form submission and review process. Without clear filing requirements in place, the Department may not have enough resources to bring filings into compliance within the prescribed timeframe, which will harm insurance companies that wish to timely enter a fully functional and competitive insurance market. It takes time to prepare an actuarial certification for unique plan designs, file the certification, and correct any deficiencies in the certification. If the level of coverage determination made by the insurer is incorrect, the insurer would also have to adjust the plan's cost sharing to comply, which would require changes to the statement of variables and accompanying summaries of benefits and coverage. Adoption of proposed section 2594.7 through the emergency rulemaking process will notify insurers of the applicable requirements prior to filing, thereby facilitating the review process. Because the levels of coverage requirement has fundamentally changed the policy submission and approval process, the ability of some insurers to sell PPACA-compliant health insurance policies this fall could be imperiled in California if proposed section 2594.7 is not adopted.

PPACA's market reforms, including the essential health benefits package, are designed to provide consumers with robust health insurance coverage subject to basic protections at the same time they are required by law to purchase health insurance. The levels of coverage requirement, in particular, will simplify comparison of health insurance products so consumers have the necessary information to purchase the best coverage for their particular situation. Even though cost sharing for benefits will vary between health insurance plans at the same level of coverage, a plan's designated level of coverage indicates the relative financial liabilities for essential health benefits coverage that will be borne by the insured and the insurer. It is therefore important that the level of coverage provided by a health insurance policy is correctly reported, as consumers will be relying on this information to make purchasing decisions and estimate their annual out-of-pocket costs for essential health benefits coverage. Consequently, adoption of section 2594.7 in this emergency rulemaking is essential to upholding the Department's mission of ensuring insurance protection for all Californians.

Given the scope of the new legal requirements reflected in Insurance Code section 10112.27, other related state law, and PPACA, and in light of the requirement that insurance companies sell, and consumers purchase, compliant policies this fall for coverage beginning January 1, 2014, it is essential that these new legal requirements be clarified, interpreted, and made specific through emergency regulation in order to provide adequate guidance and time for compliance. The existence of the emergency is especially acute given the novelty of the levels of coverage requirement and the expected increase in uptake of health insurance. Because the levels of coverage requirement is new to health insurance regulation, it is critical for the Department to enforce it in this initial year when insurers are not as familiar with the law, and when previously uninsured consumers will enter the market in response to the federal requirement to purchase health insurance. The UCLA Center for Health Policy Research and UC Berkeley Labor Center estimated that due to PPACA, an estimated 90% of Californians under age 65 will have health coverage in 2019 after PPACA is fully implemented, compared to 84% without PPACA. Much of the increase in uptake will occur within the next year because of the individual responsibility requirement, which is why these proposed regulations are urgently needed at this time.

According to a report on the 2014 health insurance market prepared by the California Health Benefits Review Program, 3.7 million Californians will be enrolled in health insurance policies regulated by the Department in 2014. Thus millions of consumers, many of whom will be new entrants to the individual and small group health insurance markets, are depending on the Department to ensure that their health insurance provides the full complement of PPACA's consumer protections, including the essential health benefits package. Without the clarity and guidance provided by these emergency regulations, there may not be insurance policies compliant with new state and federal law available for these 3.7 million Californians to purchase, or to renew for those previously insured with non-compliant policies, and thus no means by which these millions of Californians may comply with the individual responsibility requirement.

The transformation of California's individual and small group health insurance markets in PPACA's image is a goal that lawmakers, regulatory agencies, and other interested parties in the state have been pursuing since the enactment of PPACA in 2010. These proposed regulations are designed to ensure that the Department can perform its responsibility to enforce the essential health benefits package in policy form review within the allotted time, and that California's individual and small group health insurance markets are ready for the long-awaited debut of PPACA this fall, for the benefit of the state's health insurance industry and its consumers.

Studies and Reports

In this notice of proposed emergency action, the Department relied on the following studies and reports:

Ken Jacobs et. al., *Research Brief: Nine Out of Ten Non-Elderly Californians Will Be Insured When the Affordable Care Act is Fully Implemented*, UCLA Center for Health Policy Research and UC Berkeley Labor Center (June 2012), available online at http://healthpolicy.ucla.edu/publications/Documents/PDF/calsim_Exchange1.pdf (last accessed 05/15/13).

California Health Benefits Review Program, *Resource: Estimates of Sources of Health Insurance in California for 2014* (March 25, 2013), available online at http://www.chbrp.org/other_publications/docs/Estimates_of_Sources_FINAL_032513.pdf (last accessed 05/15/13).

NECESSITY OF EACH PROPOSED PROVISION TO ADDRESS DEMONSTRATED EMERGENCY

The proposed essential health benefits regulation is necessary to implement the essential health benefits package consistent with PPACA, as required by section 10112.27 of the Insurance Code. As 2014 health insurance policy forms are presently being filed with the Department for review prior to marketing for the 2014 coverage year, the guidance these regulations provide is urgently needed and will establish a basis for the policy review process, which must be completed within the next few months. The proposed regulations incorporate elements of the federal essential health benefits final rules that must be implemented and enforced in California, elaborate on the requirements for coverage of essential health benefits, and establish submission requirements and standards applicable to the preparation and review of health insurance policies for compliance with the essential health benefits package.

Section 2594. Definitions.

Section 2594 is necessary to provide definitions of terms used in the proposed regulation. Definitions and concepts from federal law are incorporated to avoid conflict and assure regulatory consistency. Although most of the definitions are derived from various federal and state statutes and regulations, section 2594 provides references to those definitions in one central location for specificity, clarity, and ease of reference.

It is necessary to define “pediatric services” in order to incorporate an eligibility age for this category of essential health benefits into state law. The eligibility age limit adopted is derived from the age provided by HHS, nineteen, in the preamble to the proposed federal rule on essential health benefits. (77 Fed. Reg. 70,644, 70,649 (November 26, 2012).)

It is necessary to define “small group health insurance policy” because the location of the definition applicable to non-grandfathered small group health insurance policies for plan years commencing on or after January 1, 2014 is in section 10753 of the Insurance Code. The definition referenced in the statute, at section 10700, will not apply to non-grandfathered small group policies in 2014 and thereafter (see Ins. Code § 10750).

It is necessary to define “treatment limitations” to interpret and make specific the statutory term through harmonizing it with the federal concept of limitations on coverage (see 45 C.F.R. § 156.115(a)(1)(ii)), and to provide specific illustrative examples for clarity.

Section 2594.1. Scope of Article.

Section 2594.1 is necessary to state the applicability of the regulations and emphasize the boundaries of the essential health benefits statute and regulations by placing all of the important provisions defining the scope of the article in one central location.

Although subsections (a), (b), and (d) duplicate several scattered provisions of section 10112.27 (subsections (a) and (f); (i); and (g), respectively), they are provided here for specificity, clarity, and ease of reference. This section provides needed clarification to insurers on the threshold issue of applicability, especially given several factors: (1) the intersection of state and federal law on excepted benefits; and (2) that the essential health benefits statute makes sections of the Health and Safety Code applicable to insurance policies for the first time.

Subdivision (c) is necessary to clarify that the applicability of the Health and Safety Code provisions enumerated in section 10112.27(a) is limited to a non-grandfathered individual or small group health insurance policy issued, amended, or renewed on or after January 1, 2014.

Subdivision (d) reiterates the rule in section 10112.27(g) to emphasize that the Insurance Code fully applies to insurance policies subject to the essential health benefits statute. Subdivision (d) is also necessary to clarify that the insurance regulations at Chapter 5 of Title 10 of the California Code of Regulations fully apply as well.

Subdivision (e) is necessary to specify that small group health insurance policies subject to section 10112.27 of the Insurance Code must comply with sections 10119.6 and 10123.141 of the Insurance Code, which require the offering of benefits that are not co-extensive with essential health benefits to purchasers of group health insurance policies.

Section 2594.2. Mandatory Coverage and Standards.

This section is necessary to codify a specific requirement to provide coverage of the essential health benefits package in state law and to provide standards for the coverage of essential health benefits that are consistent with section 10112.27 and the requirements in the final federal rule on essential health benefits.

Section 2594.2(a) reiterates the requirement to provide essential health benefits coverage found in section 10112.27(a) and is included here to provide structure and clarity. Omission of this basic rule from these proposed regulations would result in confusion and is therefore necessary for clarity.

Section 2594.2(b) specifies that coverage of the essential health benefits package, as defined in section 1302(a) of PPACA, is required. This provision is necessary to implement section 10112.27 consistent with PPACA, as required by section 10112.27(j).

Section 2594.2(c) is necessary to adopt a similarity standard for coverage of essential health benefits as compared to the base-benchmark plan, CHIP, and FEDVIP. This provision adopts the substantially equal standard in 45 C.F.R. section 156.115(a)(1)(i).

Section 2594.2(d) is necessary to interpret and make specific the requirement under section 10112.27(b) that treatment limitations on essential health benefits coverage shall be no greater than the limitations imposed by the base-benchmark plan, the CHIP plan for pediatric oral essential health benefits, and FEDVIP for pediatric vision essential health benefits. The statutory term “treatment limitation” is defined in section 2594 consistent with the concept of “limitations on coverage” from the federal essential health benefits rule (see 45 C.F.R. § 156.115(a)(1)(ii)). This provision also clarifies, consistent with section 10112.27(b), that treatment limitations are governed by other applicable laws and regulations, including regulations pertaining to mental health parity.

Section 2594.2(e) is necessary to align California law with federal law by adopting the rule in 45 C.F.R. section 156.115(a)(2) specifying that an individual cannot be excluded from coverage for essential health benefits except that an individual who does not meet the eligibility age for pediatric services may be excluded from coverage for pediatric services.

Section 2594.2(f) is necessary to interpret and make specific the prohibition in section 10112.27(c) against substitution of benefits. 45 C.F.R. section 156.115(b) permits substitution of actuarially equivalent benefits, except prescription drug benefits, within essential health benefit categories unless substitution is prohibited by state law. Section 2594.2(f) unequivocally states that substitution of benefits within essential health benefit categories is prohibited.

Section 2594.2(g) is necessary to interpret and make specific the habilitative services and devices coverage requirement in section 10112.27(a)(1), consistent with the rules provided in section 10112.27(a)(3), as well as 45 C.F.R. section 156.110(f).

Section 2594.2(h) is necessary to adopt the explicit prohibition against discrimination in benefit design, or the implementation of benefit design, in 45 C.F.R. section 156.125, as well as to incorporate additional protected classes from section 10140 of the Insurance Code.

Section 2594.3. Essential Health Benefits.

This section is necessary to elaborate on the definition of essential health benefits provided in section 10112.27(a). This section provides a free-standing, complete definition of essential health benefits for purposes of clarity by including elements of section 10112.27(a), as well as additional clarifying elements. It is necessary to duplicate the statute to promote clarity, as omission of elements of essential health benefits could create confusion.

Section 2594.3(a)(1) references the statutory list of the ten essential health benefit categories in section 10112.27(a)(1) to provide structure and clarity. Omission of this basic rule from these proposed regulations would result in confusion and is therefore necessary for clarity.

Section 2594.3(a)(2) reiterates the requirement to cover basic health care services in section 10112.27(a)(2)(A)(i). It is restated here to provide a complete definition of essential health benefits in the regulation, which is necessary for structure and clarity. Omission of this basic rule from these proposed regulations would result in confusion.

Section 2594.3(a)(3) specifies that essential health benefits include health benefits that were mandated to be covered by the base-benchmark plan pursuant to statutes enacted before December 31, 2011, including all of the following mandates: (A) the sections of the Health and Safety Code enumerated in sections 10112.27(a)(2)(A)(ii) and (iv); (B) the benefits mandated to be covered by 28 C.C.R. section 1300.67.24(a) (outpatient prescription drugs); and (C) the benefits mandated to be covered by 28 C.C.R. section 1300.68.2 (hospice care). 28 C.C.R. section 1300.68.2 provides detail on the specific benefits that must be covered pursuant to Health and Safety Code section 1368.2, which is enumerated in section 10112.27(a)(2)(A)(ii). This provision is necessary to specify the applicable mandates and to provide them in one central location for structure and clarity.

Section 2594.3(a)(4) is necessary to specify the durable medical equipment for home use and prosthetic and orthotic devices that are essential health benefits because the base-benchmark plan covered them during the first quarter of 2012. The evidence of coverage for the base-benchmark plan refers to a durable medical equipment formulary that is not publicly available. Therefore, this provision descriptively lists all the durable medical equipment that was covered, whether indicated as such in the evidence of coverage, the formulary, or both. This provision is necessary to provide notice of all the durable medical equipment for home use and prosthetic and orthotic devices that are essential health benefits to ensure that insurers provide coverage that is substantially equal to the base-benchmark plan.

Section 2594.3(a)(5) is necessary to identify health benefits covered by the base-benchmark plan that were not covered pursuant to applicable state mandates. These benefits are essential health benefits per section 10112.27(a)(2)(A)(v). This provision provides insurers with notice of the benefits that must be explicitly covered in policy forms under section 10112.27(a)(2)(A)(v).

Section 2594.3(a)(6) is necessary to implement and interpret subdivisions (a)(4) and (a)(5) of section 10112.27, which designate the plans from which pediatric vision and oral essential health benefits, respectively, are derived. Under subdivision (a)(6)(A)(iii), orthodontic care is an essential health benefit when medically necessary pursuant to the standard in the federal Children's Health Insurance Program Reauthorization Act of 2009, as stated in the regulation.

Section 2594.3(b)(1) is necessary to exclude routine non-pediatric eye exam services from the definition of essential health benefits to align state law with the requirement in 45 C.F.R. section 156.115(d). The base-benchmark plan covered preventive vision screenings and eye exams for refraction to determine the need for vision correction and to provide a prescription for eyeglass lenses. The Department interprets the federal provision to require the exclusion of non-pediatric eye exam services for refraction to determine the need for vision correction and provide a prescription for eyeglass lenses, but not to exclude coverage for preventive eye exams and vision screenings. Although federal law precludes the inclusion of coverage for non-pediatric eye exams to provide a prescription for corrective eyeglass lenses as an essential health benefit, insurers may cover the benefit voluntarily if they so choose.

Section 2594.3(b)(2) reiterates the rule in section 10112.27(q) that essential health benefits do not include the network limitations or cost sharing provisions of the base-benchmark plan, CHIP,

or FEDVIP. It is necessary to duplicate the statute here to provide structure for the regulation as well as for clarification of this important point, as this is a common source of confusion among insurers given that the base-benchmark plan is a health care service plan subject to different legal requirements.

Section 2594.4. Prescription Drug Coverage.

Section 2594.4(a) is necessary to specify in one central location that prescription drug coverage is subject to several sections of the Health and Safety Code enumerated in the statute, the outpatient prescription drug regulation at 28 C.C.R. section 1300.67.24, and the federal rule at 45 C.F.R. section 156.122(a)(1). The federal rule provides that an issuer must cover at least the greater of one drug in every United States Pharmacopeia (“USP”) category and class or the same number of prescription drugs covered by the benchmark plan in each USP category and class. This section integrates that rule into California law. All of these requirements are newly applicable to individual and small group health insurance policies, and their placement in a section the subject of which is prescription drug coverage will provide clarity for health insurers.

Section 2594.4(b) requires, as part of the policy form submission requirement under section 10290 of the Insurance Code, that health insurers submit the following: (1) A list reporting the number of chemically distinct drugs covered in each United States Pharmacopeia category and class and an attestation to the truth and accuracy of the list; (2) Any prescription drug list and/or formulary associated with the policy form; (3) Consumer documents describing prescription drug benefits and limitations on coverage, including any prescription drug list and/or formulary associated with the policy form that is provided to consumers; and (4) An attestation of compliance with section 1300.67.24 of Title 28 of the California Code of Regulations.

Submission of the requested information is necessary for enforcement of the law applicable to coverage of prescription drugs. Submission of number (1), a self-reported list and attestation of the number of chemically distinct drugs covered in each USP category and class, is necessary to assist the Department in evaluating compliance with 45 C.F.R. section 156.122(a)(1). Submission of number (2), the prescription drug list and/or formulary, is necessary so the Department may independently verify compliance with various legal requirements, including 45 C.F.R. section 156.122(a)(1), and is required under 45 C.F.R. section 156.122(a)(2). Submission of number (3), consumer documents, is necessary to verify that documents provided to consumers describing prescription drug coverage are accurate and reflect applicable California law. Submission of number (4) is necessary to verify that insurers are complying with the outpatient prescription drug regulation at 28 C.C.R. section 1300.67.24, which was newly made applicable to insurers by section 10112.27.

Section 2594.5. Annual Limitations on Cost Sharing and Small Group Deductibles.

This section adopts PPACA’s annual limitations on cost sharing and small group deductibles, exactly as specified in federal law and regulations. This section is necessary to implement section 10112.27 consistent with PPACA, as required by section 10112.27(j), and to provide the Department with explicit authority to enforce this component of the essential health benefits package.

Section 2594.5(a) is necessary to specify in state law that individual and small group health insurance policies must comply with PPACA's annual limitation on cost sharing for essential health benefits.

Section 2594.5(b) is necessary to specify in state law that small group health insurance policies must comply with PPACA's annual limitation on small group deductibles.

Section 2594.5(c) is necessary to incorporate the federal rules at 45 C.F.R. section 156.130(g) concerning limitations on coverage for out-of-network emergency services and cost sharing for out-of-network emergency services into state law.

Section 2594.6. Levels of Coverage for Essential Health Benefits.

The purpose of this section is three-fold: (1) to clarify the requirement under subdivision (b) of section 10112.3 that "[h]ealth insurers participating in the Exchange must 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 [PPACA];" (2) to incorporate the federal rules governing catastrophic plans at 45 C.F.R. 156.155 into state law; and (3) to require health insurance policies to prominently disclose the level of coverage provided. This section is necessary to implement section 10112.27 consistent with PPACA, as required by section 10112.27(j), and to interpret section 10112.3(b) and (d).

Section 1302(e) of PPACA, as well as the definition of catastrophic plans at 45 C.F.R. section 156.155(a), specify that catastrophic plans may be offered only on the individual market. Consequently, health insurers participating in the small group Exchange market may not sell catastrophic plans, as would be required by a literal interpretation of section 10112.3(b). Additionally, section 10112.3(d) could be interpreted to provide implicit authority for any health insurer participating in the Exchange, regardless of market, to provide catastrophic coverage even though under federal law catastrophic plans are limited to the individual market.

Section 2594.6(a) is necessary to make specific the requirement under section 10112.3(d) that an individual health insurance policy may provide the four metal levels of coverage, as well as catastrophic coverage, subject to the limitation in section 10112.3(d) that health insurers not participating in the Exchange may not sell catastrophic plans. This provision also incorporates two federal regulations by reference: (1) 45 C.F.R. section 156.140, which specifies the acceptable de minimis variation in actuarial value from the percentages for each level of coverage required under PPACA; and (2) 45 C.F.R. section 156.155, which prescribes rules for catastrophic plans that must be enforced by the Department in policy review.

Section 2594.6(b) is necessary to interpret sections 10112.3(b) and (d) in light of federal law by clarifying that a small group health insurance policy may provide only the four metal levels of coverage, and not catastrophic coverage.

Section 2594.6(c) is necessary to adopt a specific requirement for health insurance policies to prominently disclose the level of coverage provided. This disclosure requirement is intended to

ensure that consumers are aware of the level of coverage provided by the health insurance plans they consider purchasing and ultimately select.

Section 2594.7. Demonstration of Actuarial Value for Essential Health Benefits.

This section implements the levels of coverage component of the essential health benefits package through specifying submission requirements for insurer verification of actuarial value together with policy forms and incorporating the federal requirements for determining the actuarial value of plans that are compatible, and incompatible, with the federal Actuarial Value Calculator. This section adopts the requirements of 45 C.F.R. section 156.135(b), thus providing the Department with explicit authority to require the federally-prescribed mechanism (actuarial certifications using one of the two methods described therein) for the demonstration and review of unique (incompatible) plan designs for actuarial value. This section is necessary to implement section 10112.27 consistent with PPACA, as required by section 10112.27(j), and to implement, interpret, and make specific section 10112.3(d).

Section 2594.7(a) is necessary to specify the documentation that must be submitted together with a health insurance policy form under section 10290 of the Insurance Code to demonstrate actuarial value for each level of coverage provided.

Subdivision (a)(1) provides that a statement of variables must be submitted that specifies the cost sharing values for all health benefits subject to cost sharing for each level of coverage provided. This provision is necessary to require specification of cost sharing values for each level of coverage provided by the health insurance product, as the values affect the actuarial value of each plan and therefore cannot vary. A statement of variables is required because one identical policy form may be used for all levels of coverage (plans) if the policy form contains variables for the benefits subject to cost sharing. For example, the value for the annual limitation on cost sharing in the policy form would be contained in variable bracket [a], the value for the deductible would be contained in variable bracket [b], the value of the copayment or coinsurance for an outpatient physician visit would be contained in variable bracket [c], and so on. The statement of variables would then specify the values for [a], [b], [c], etc., for each level of coverage provided by the product.

Subdivision (a)(2) is necessary to provide the Department with the inputs to the federal Actuarial Value Calculator used to obtain the actuarial value for each level of coverage provided. This information must be checked against the policy form and statement of variables to verify that it was correctly entered. This provision is necessary to implement a mechanism for verifying actuarial value consistent with the rule in 45 C.F.R. section 156.135(a) that the federal Actuarial Value Calculator must be used to calculate the actuarial value of a plan which is compatible with the calculator.

Subdivision (a)(3) provides that if the benefit design is incompatible with the federal Actuarial Value Calculator, the insurer must submit an actuarial certification of the methodology chosen to determine actuarial value from the two options specified in 45 C.F.R. section 156.135(b). This provision is necessary to adopt the mechanism for verifying actuarial value for unique plan designs that is provided for in the federal regulation.

Section 2594.7(b) is necessary to specify the required contents of a statement of variables. A statement of variables specifies the cost sharing values for all health benefits subject to cost sharing under the policy. Proper construction of a statement of variables indicating the cost sharing values for each level of coverage, or plan, provided by the health insurance policy form obviates a need to submit a separate policy form for each plan.

Section 2594.7(c) details the required components of actuarial certifications for plan designs that are incompatible with the federal Actuarial Value Calculator. This provision adopts the federal standard for determining compatibility with the calculator described in the final federal rule on essential health benefits at 78 Fed. Reg. 12,834, 12,850 (February 25, 2013).

This provision provides that: the actuary preparing the certification must have the requisite professional qualifications (subdivision (c)(1)); the certification must contain an adequate description of the methodology chosen to determine actuarial value from the two options specified in 45 C.F.R. section 156.135(b), including verification of certain elements required under that rule ((c)(2)); and the certification must contain a statement of opinion from the certifying actuary attesting that the prescribed methods for determining actuarial value were employed appropriately ((c)(3)). This provision is necessary to adopt specific standards for the preparation and contents of actuarial certifications for unique plan designs so the Department receives adequate documentation of actuarial value and can ensure that individual and small group health insurance products provide the levels of coverage required under section 10112.3(d).

Section 2594.7(d) specifies that when the actuarial values associated with a previously submitted policy form are no longer within the allowable range for the levels of coverage provided for by 45 C.F.R. section 156.140, i.e. plus or minus 2% from the designated actuarial value, a health insurer must re-file with the Department to bring the product back into compliance. Because cost and utilization of essential health benefits will increase over time, cost sharing must be adjusted to maintain actuarial value within the prescribed range. This provision provides the option to submit only an updated statement of variables along with the documentation necessary to demonstrate actuarial value if changes to the text of the previously submitted policy form are unnecessary; otherwise a complete updated filing is required. This section is necessary to clarify that updated statements of variables with adjusted cost sharing values for existing products must be filed with the Department to maintain compliance with levels of coverage, as the actuarial value will extend out of range if cost sharing is held constant indefinitely.

Section 2594.7(e) provides that a small group health insurance policy offered in conjunction with a health savings account or an integrated health reimbursement arrangement to which an employer makes annual contributions and that may only be used for cost sharing, and which is taken into account in determining actuarial value, must include either specific values for the contribution, or a range of values for the contribution, in the accompanying statement of variables. If a statement of variables with a range of values for the annual employer contribution is filed, the insurer must demonstrate that the actuarial value remains within the allowable range for the levels of coverage provided by submitting verification of actuarial value for the minimum and maximum employer contributions in the range. This provision is necessary to account for

subsection (c) of section 156.135 of Title 45 of the Code of Federal Regulations by incorporating the allowance for counting employer contributions toward actuarial value into the Department's requirements for demonstrating actuarial value.

Section 2594.7(f) provides that a stand-alone pediatric dental plan, which is a specialized health insurance policy certified by the Exchange that covers, at a minimum, the pediatric oral essential health benefit, must comply with the requirements at 45 C.F.R. section 156.150, including set actuarial values of either 70% or 85% for pediatric dental essential health benefits, and that an actuarial certification must be submitted to the Department together with the policy form. The required contents of an actuarial certification for stand-alone pediatric dental plans parallel the requirements for health insurance plans discussed above for section 2594.7(c), except that details specific to the method of calculating actuarial value have been changed to reflect differences in the federal rules applicable to stand-alone pediatric dental plans and health insurance policies. This provision is necessary to adopt the actuarial value requirements in the federal rule and establish a mechanism for the enforcement of those requirements in the policy review process.