On February 28, 2013, the Assembly Committee on Health requested that CHBRP analyze AB 889, as introduced. On March 11, 2013, the Assembly Committee on Health requested CHBRP analyze AB 889, as the bill will be amended as indicated by the Bill Author.
Below is the text of the bill as will be amended as indicated by the Bill Author. Following is the bill as introduced.

AB 889—As proposed to be amended 3/11/2013

Amendments to AB 889 (Frazier)

(a) Notwithstanding any other provision of law, a health care service plan that restricts medications pursuant to step therapy or fail first protocol shall be subject to the requirements of this section.

(b) Have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care.

(c) The duration of any step therapy or fail first protocol shall be consistent with up-to-date evidence-based outcomes and current published peer-reviewed medical and pharmaceutical literature.

(d) The health care service plan shall not require a patient to try and fail on more than two medications before allowing the patient access to the medication, or generically equivalent drug, prescribed by the prescribing participating plan provider, unless the FDA-approved label indication, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested medications.

(e) For purposes of this section, a "prescribing participating plan provider" shall include a provider who is authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(f) For the purposes of this section, "generically equivalent drug" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(g) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for a prescription drug benefit or from setting forth by contract a limitation on maximum coverage of prescription drug benefits, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and communicated to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(h) Nothing in this section shall be construed to require coverage of prescription drugs not in a plan's drug formulary or to prohibit generically equivalent drugs or generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.

Identical language to be added to the Insurance Code

AB 889—As Introduced

An act to amend Sections 1342.7 and 1374.30 of the Health and Safety Code, and to amend Section 10169 of, and to add Section 10123.193 to, the Insurance Code, relating to health care coverage.

Legislative Counsel's Digest

AB 889, as introduced, Frazier. Health care coverage.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. Existing law requires health care service plan contracts to provide specified coverage to enrollees and subscribers, including specified benefits regarding prescription drugs. Existing law requires the department to develop a regulation outlining standards to be used in reviewing a plan's request for approval of its proposed copayment, deductible, limitation, or exclusion on its prescription drug benefits, and to consider alternative benefit designs in developing those standards. Existing law makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance.

This bill would delete those provisions regarding development of a regulation outlining the standards to be used in reviewing a plan's request for approval. The bill instead would codify the department's regulation and require every health care service plan or health insurance policy that provides coverage for outpatient prescription drug benefits, as defined, to provide coverage for all medically necessary outpatient prescription drugs, except as specified. The bill would set forth

additional standards regarding outpatient prescription drug benefits, including requiring a plan or insurer seeking to establish limitations or exclusions on outpatient prescription drug benefits to establish those limitations or exclusions consistent with up-to-date evidence-based outcomes and current published, peer-reviewed medical and pharmaceutical literature. The bill would also place restrictions on copayments, coinsurance and deductibles, including, among other things, prohibiting a copayment or percentage coinsurance from exceeding 50% of the cost to the plan or insurer.
Existing law establishes the Independent Medical Review System in the Department of Managed Health Care and the Department of Insurance. Existing law authorizes an enrollee or an insured to apply to the department for an independent medical review of a decision to deny, modify, or delay health care services, based in whole or in part on a finding that the disputed health care services are not medically necessary, within 6 months of any specified qualifying periods or events. Existing law requires all necessary information and documents to be delivered to an independent medical review organization within 24 hours of approval of the request for review if there is an imminent and serious threat to the health of the enrollee, as specified.
This bill would authorize an enrollee or an insured or an enrollee's or insured's provider or the respective departments to request an expeditious medical review of denied, modified, or delayed health care services if there is an imminent and serious threat to the health of the enrollee or insured, as specified.
Because a willful violation of these requirements with respect to health care service plans would be a crime, the bill would impose a state-mandated local program.
The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.
This bill would provide that no reimbursement is required by this act for a specified reason.
Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.
The people of the State of California do enact as follows:

1 SECTION 1. Section 1342.7 of the Health and Safety Code is line 2 amended to read:

1 1342.7. (a) The Legislature finds that in enacting Sections line 2 1367.215, 1367.25, 1367.45, 1367.51, and 1374.72, it did not line 3 intend to limit the department's authority to regulate the provision line 4 of medically necessary prescription drug benefits by a health care line 5 service plan to the extent that the plan provides coverage for those line 6 benefits.

7 (b) (1) Nothing in this chapter shall preclude a plan from filing 8 relevant information with the department pursuant to Section 1352 9 to seek the approval of a copayment, deductible, limitation, or 10 exclusion to a plan's prescription drug benefits. If the department 11 approves an exclusion to a plan's prescription drug benefits, the 12 exclusion shall not be subject to review through the independent 13 medical review process pursuant to Section 1374.30 on the grounds 14 of medical necessity. The department shall retain its role in 15 assessing whether issues are related to coverage or medical 16 necessity pursuant to paragraph (2) of subdivision (d) of Section 17 1374.30.

18 (2) A plan seeking approval of a copayment or deductible may 19 file an amendment pursuant to Section 1352.1. A plan seeking 20 approval of a limitation or exclusion shall file a material 21 modification pursuant to subdivision (b) of Section 1352.

22 (c) Nothing in this chapter shall prohibit a plan from charging 23 a subscriber or enrollee a copayment or deductible for a 24 prescription drug benefit or from setting forth by contract, a 25 limitation or an exclusion from, coverage of prescription drug 26 benefits, if the copayment, deductible, limitation, or exclusion is 27 reported to, and found unobjectionable by, the director and 28 disclosed to the subscriber or enrollee pursuant to the provisions 29 of Section 1363.

(d) Every health care service plan that provides coverage for line 31 outpatient prescription drug benefits shall provide coverage for line 32 all medically necessary outpatient prescription drugs, except as line 33 described in this section.

(1) "Outpatient prescription drugs" are self-administered drugs line 35 approved by the federal Food and Drug Administration for sale line 36 to the public through retail or mail order pharmacies that require line 37 prescriptions and are not provided for use on an inpatient basis.

(2) Coverage for outpatient prescription drugs shall include line 39 coverage for disposable devices that are medically necessary for line 40 the administration of a covered outpatient prescription drug, such

(e) Standards for an outpatient prescription drug benefit shall line 9 be as follows:

(1) An outpatient prescription drug benefit offered by a plan line 11 shall comply with the requirements of this chapter and the line 12 regulations promulgated by the director, including, but not limited line 13 to, Sections 1342, 1343.5, 1342.7, 1363, 1363.01, 1363.03, 1363.5, line 14 1367.01, 1367.06, 1367.20, 1367.21, 1367.22, 1367.24, and line 15 subdivisions (e), (g), and (h) of Section 1367, of this chapter, and line 16 subparagraph (A) of paragraph (3) of subdivision (a) of Section line 17 1300.67.4 of Title 28 of the California Code of Regulations.

(2) All clinical aspects of a plan's outpatient prescription drug line 19 benefit shall be developed by qualified medical and pharmacy line 20 professionals in accordance with good professional practice. The line 21 plan shall establish and document an internal process for ongoing line 22 review by qualified medical and pharmacy professionals of the line 23 clinical aspects of the outpatient prescription drug benefit, line 24 including review of limitations and exclusions, and the safety, line 25 efficacy, and utilization of an outpatient prescription drugs, line 26 including step therapy, if any.

(3) Plans seeking to establish limitations or exclusions on an

(4) A plan that provides coverage for outpatient prescription line 32 drugs through a mail order pharmacy shall have written policies line 33 and procedures documenting that the plan's mail order line 34 arrangements are in compliance with the requirements of this line 35 chapter, and applicable California and federal laws regarding line 36 pharmacists and pharmacy services. The mail order pharmacy line 37 process shall conform effectively and efficiently with a plan's line 38 processes for prior authorization for coverage of medically line 39 necessary drugs as required by this chapter, and shall include line 40 standards for timely delivery and a contingency mechanism for

(5) In reviewing copayments, coinsurance, deductibles, line 4 limitations, or exclusions for compliance with subdivisions (e) and line 5 (h) of Section 1367 and subparagraph (A) of paragraph (3) of line 6 subdivision (a) of Section 1300.67.4 of Title 28 of the California line 7 Code of Regulations, the department's approval or disapproval line 8 may be based upon all relevant factors, including, but not limited line 9 to, the following:

(A) The type and number of enrollees affected.

(B) The clinical efficacy of the drug or drugs proposed to be line 12 limited or excluded.

(C) The availability of therapeutic equivalents or other drugs line 14 medically necessary for treatment of health conditions.

(D) The specific health plan products to which the copayment, line 16 coinsurance, deductible, limitation, or exclusion will apply.

(E) The duration of the limitation or exclusion.

(F) The rationale for the copayment, coinsurance, deductible, line 19 limitation, or exclusion.

(G) The projected effect of the copayment, coinsurance, line 21 deductible, limitation, or exclusion on the affordability and line 22 accessibility of coverage.

(H) The projected comparative clinical effect, including any line 24 potential risk of adverse health outcomes, based upon utilization line 25 data and review of peer-reviewed professional literature.

(I) The overall copayment structure of the product, including line 27 whether the copayment, coinsurance, or deductible contributes to line 28 the overall out-of-pocket maximum for the product.

(J) Information regarding similar copayments, coinsurance line 30 levels, deductibles, limitations, or exclusions previously approved line 31 by the department.

(K) Evidence-based clinical studies and professional literature.

(L) The description of the copayment, coinsurance, deductible, line 34 limitation, or exclusion as compared to other benefits and products line 35 in the marketplace.

(M) Any other historical, statistical, or other information that line 37 the submitting plan considers pertinent to the request for approval line 38 of the copayments, coinsurance level, deductibles, limitation, or line 39 exclusion.

(f) Copayments, coinsurance, and deductibles shall be consistent line 2 with Sections 1367.006, 1367.007, 1367.009, and 1366.6.

(1) A plan's outpatient prescription drug benefit shall provide line 4 that if the pharmacy's retail price for a prescription drug is less line 5 than the applicable copayment amount, the enrollee shall not be line 6 required to pay any more than the retail price.

(2) Proposed copayment structures or ranges, coinsurance, or line 8 deductibles submitted to the director for approval shall be based line 9 upon a methodology that is fully described and documented, and line 10 that complies with the standards set forth in this section. A plan line 11 may use actual cost data on prescription drugs or, for contracted line 12 services or products, nationally recognized data sources used by line 13 the plan in developing the contract rates.

(3) A copayment or percentage coinsurance shall not exceed line 15 50 percent of the cost to the plan. A percentage coinsurance shall line 16 meet each of the following additional requirements:

(A) Have a maximum dollar amount cap on the percentage line 18 coinsurance that will be charged for an individual prescription.

(B) Apply towards an annual out-of-pocket maximum for the line 20 product.

(C) Apply towards an annual out-of-pocket maximum for the line 22 outpatient prescription drug benefit, if any.

(4) In addition to compliance with this subdivision, copayments line 24 and coinsurances shall comply with the standards identified at line 25 subdivision (e), including that they shall be reasonable so as to line 26 allow access to medically necessary outpatient prescription drugs, line 27 and the department's determination may be based on all relevant line 28 factors as provided in paragraph (5) of subdivision (e).

(5) As used in paragraph (3), the "cost to the plan" means the line 30 actual cost incurred by the plan or its contracting provider to line 31 acquire and dispense a covered outpatient prescription drug, line 32 without subtracting or otherwise considering any copayment or line 33 coinsurance amount to be paid by enrollees. The cost to the plan line 34 may include average cost calculations as described in this section, line 35 and shall include all discounts and other prospective cost and line 36 pricing arrangements, as applicable. Plans shall account for any line 37 rebates and other retrospective cost and pricing arrangements for line 38 outpatient prescription drugs by verifying that the rebates and line 39 other retrospective cost and pricing arrangements for outpatient

(g) Plans that provide coverage for outpatient prescription drug line 4 benefits may apply the following limitations:

(1) A plan may impose prior authorization requirements on line 6 outpatient prescription drug benefits, consistent with the line 7 requirements of this chapter and corresponding regulations.

(2) When there is more than one drug that is appropriate for line 9 the treatment of a medical condition, a plan may require step line 10 therapy. A plan that requires step therapy shall have an expeditious line 11 process in place to authorize exceptions to step therapy when line 12 medically necessary and to conform effectively and efficiently with line 13 continuity of care requirements of this chapter and regulations. line 14 In circumstances where an enrollee is changing plans, the new line 15 plan may not require the enrollee to repeat step therapy when that line 16 enrollee is already being treated for a medical condition by an line 17 outpatient prescription drug, provided that the drug is line 18 appropriately prescribed and is considered safe and effective for line 19 the enrollee's condition. Nothing in this section shall preclude the line 20 new plan from imposing a prior authorization requirement line 21 pursuant to Section 1367.24 for the continued coverage of an line 22 outpatient prescription drug prescribed pursuant to step therapy line 23 imposed by the former plan, or preclude the prescribing provider line 24 from prescribing another drug covered by the new plan that is line 25 medically appropriate for the enrollee. Step therapy, including the line 26 expeditious process for exception and the instances when an line 27 enrollee is changing plans, shall be subject to subdivision (e). For line 28 purposes of this section, "step therapy" means a protocol that line 29 specifies the sequence in which different prescription drugs for a line 30 given medical condition that are medically appropriate for a line 31 particular patient are to be prescribed.

(3) A plan shall provide coverage for the medically necessary line 33 dosage and quantity of the drug prescribed for the treatment of a line 34 medical condition consistent with professionally recognized line 35 standards of practice.

(A) A plan may limit the amount of the drug dispensed at any line 37 one time to a 30-day supply or, if the treatment is for less than 30 line 38 days, for the medically necessary amount of the drug.

(B) A plan may impose a requirement that maintenance drugs line 40 be dispensed in a two-month or greater supply.

(C) A plan may establish a mandatory mail order process for line 2 maintenance drugs when dispensed in a three-month supply or line 3 greater quantities, but shall not impose any fees or costs for line 4 mandatory mail order prescriptions other than the applicable line 5 copayment or coinsurance. A plan shall not require an enrollee line 6 to fill a prescription by mail if the prescribed drug is not available line 7 to be filled in that manner.

(D) For purposes of this section, "maintenance drugs" means line 9 those outpatient prescription drugs that are prescribed for the line 10 enrollee on a continual basis to treat a chronic condition.

(4) Plans may require enrollees who are prescribed drugs for line 12 smoking cessation to be enrolled in or to have completed a smoking line 13 cessation program, if covered by the plan prior to or concurrent line 14 with receiving the prescription drug.

(5) Other limitations that the department may approve pursuant line 16 to this section.

(h) Plans that provide coverage for outpatient prescription drug line 18 benefits are not required to provide coverage for prescription line 19 drugs that meet any of the following conditions:

(1) When prescribed for cosmetic purposes. For purposes of line 21 this section "cosmetic purposes" means solely for the purpose of line 22 altering or affecting normal structures of the body to improve line 23 appearance rather than function.

(2) When prescribed solely for the treatment of hair loss, sexual line 25 dysfunction, athletic performance, anti-aging for cosmetic line 26 purposes, and mental performance. Drugs for mental performance line 27 shall not be excluded from coverage when they are used to treat line 28 diagnosed mental illness or medical conditions affecting memory, line 29 including, but not limited to, treatment of the conditions or line 30 symptoms of dementia or Alzheimer's disease.

(3) When prescribed solely for the purposes of losing weight, line 32 except when medically necessary for the treatment of morbid line 33 obesity. Plans may require enrollees who are prescribed drugs line 34 for morbid obesity to be enrolled in a comprehensive weight loss line 35 program, if covered by the plan, for a reasonable period of time line 36 prior to or concurrent with receiving the prescription drug.

(4) When prescribed solely for the purpose of shortening the line 38 duration of the common cold.

(5) Drugs that are available over the counter. A plan shall not line 40 exclude coverage of an entire class of prescription drugs when

(6) Replacement of lost or stolen drugs.

(7) When prescribed by noncontracting providers for line 9 noncovered procedures that are not authorized by a plan or a plan line 10 provider except when coverage is otherwise required in the context line 11 of emergency services.

(8) Other categories of prescription drugs approved by the line 13 department pursuant to this section.

(i) A plan shall have written policies and procedures for its line 15 outpatient prescription drug benefits, and quality assurance line 16 systems in place for the early identification and swift correction line 17 of problems in the accessibility and availability of outpatient line 18 prescription drug benefits. A contract between a health care service line 19 plan and a prescription drug benefit provider shall include line 20 provisions, terms, and conditions sufficient to ensure that the line 21 standards and requirements of this section are met.

(j) (1) Any exclusion or limitation on an outpatient prescription line 23 drug benefit that is not described in subdivision (g) or (h) shall line 24 not be applied to a plan's outpatient prescription drug benefit line 25 unless a plan has filed a notice of material modification with the line 26 department and received approval by order to apply the exclusion line 27 or limitation. The order of approval may be issued subject to line 28 specified terms and conditions, or for specified periods, as the line 29 department may determine are necessary and appropriate. line 30 Following issuance of an order approving an exclusion or line 31 limitation, any other health care service plan may apply the same line 32 exclusion or limitation to its outpatient prescription drug benefit line 33 if it files an amendment with the department not less than 30 days line 34 prior to implementation of the exclusion or limitation, and line 35 represents that it is exactly the same as that previously approved line 36 by order, provides specific reference to the order number and date line 37 issued, and addresses any specified terms and conditions upon line 38 that order, as applicable.

(2) A plan may meet the material modification filing line 40 requirements of paragraph (1) with respect to exclusions and

or amended line 2 on or before January 1, 2007, by filing within six months of the line 3 effective date of Section 1300.67.4 of Title 28 of the California line 4 Code of Regulations a report disclosing and describing all such line 5 exclusions and limitations on prescription drug benefits covered line 6 under all subscriber contracts subject to the requirements of this line 7 section. The department will provide an expeditious review of the line 8 exclusions and limitations disclosed in the report.

(d) The department in developing standards for the approval of 10 a copayment, deductible, limitation, or exclusion to a plan's 11 prescription drug benefits, shall consider alternative benefit 12 designs, including, but not limited to, the following:

(1) Different out-of-pocket costs for consumers, including 14 copayments and deductibles.

(2) Different limitations, including caps on benefits.

(3) Use of exclusions from coverage of prescription drugs to 17 treat various conditions, including the effect of the exclusions on 18 the plan's ability to provide basic health care services, the amount 19 of subscriber or enrollee premiums, and the amount of 20 out-of-pocket costs for an enrollee.

(4) Different packages negotiated between purchasers and plans.

(5) Different tiered pharmacy benefits, including the use of 23 generic prescription drugs.

(6) Current and past practices.

(e) The department shall develop a regulation outlining the 26 standards to be used in reviewing a plan's request for approval of 27 its proposed copayment, deductible, limitation, or exclusion on its 28 prescription drug benefits.

(f)

Nothing in subdivision (b) or (c) shall permit a plan to limit 31 prescription drug benefits provided in a manner that is inconsistent 32 with Sections 1367.215, 1367.25, 1367.45, 1367.51, and 1374.72.

(g)

l) Nothing in this section shall be construed to require or 35 authorize a plan that contracts with the State Department of Health 36 Services to provide services to Medi-Cal beneficiaries or with the 37 Managed Risk Medical Insurance Board to provide services to 38 enrollees of the Healthy Families Program to provide coverage for 39 prescription drugs that are not required pursuant to those programs

1 or contracts, or to limit or exclude any prescription drugs that are 2 required by those programs or contracts.

(h)

Nothing in this section shall be construed as prohibiting or 5 otherwise affecting a plan contract that does not cover outpatient 6 prescription drugs, *as defined in subdivision (d),* except for 7 coverage for limited classes of prescription drugs because they are 8 integral to treatments covered as basic health care services, 9 including, but not limited to, immunosuppressives, in order to 10 allow for transplants of bodily organs.

(i)

The department shall periodically review its regulations 13 developed pursuant to this section.

(j) This section shall become operative on January 2, 2003, and 15 shall only apply to contracts issued, amended, or renewed on or 16 after that date.

17 SEC. 2. Section 1374.30 of the Health and Safety Code, as line 18 amended by Section 1 of Chapter 872 of the Statutes of 2012, is line 19 amended to read:

20 1374.30. (a) Commencing January 1, 2001, there is hereby line 21 established in the department the Independent Medical Review line 22 System.

23 (b) For the purposes of this chapter, "disputed health care 24 service" means any health care service eligible for coverage and 25 payment under a health care service plan contract that has been 26 denied, modified, or delayed by a decision of the plan, or by one 27 of its contracting providers, in whole or in part due to a finding 28 that the service is not medically necessary. A decision regarding 29 a disputed health care service relates to the practice of medicine 30 and is not a coverage decision. A disputed health care service does 31 not include services provided by a specialized health care service 32 plan, except to the extent that the service (1) involves the practice 33 of medicine, or (2) is provided pursuant to a contract with a health 34 care service plan that covers hospital, medical, or surgical benefits. 35 If a plan, or one of its contracting providers, issues a decision 36 denying, modifying, or delaying health care services, based in 37 whole or in part on a finding that the proposed health care services 38 are not a covered benefit under the contract that applies to the 39 enrollee, the statement of decision shall clearly specify the 40 provision in the contract that excludes that coverage.

1 (c) For the purposes of this chapter, “coverage decision” means 2 the approval or denial of health care services by a plan, or by one 3 of its contracting entities, substantially based on a finding that the 4 provision of a particular service is included or excluded as a 5 covered benefit under the terms and conditions of the health care 6 service plan contract. A “coverage decision” does not encompass 7 a plan or contracting provider decision regarding a disputed health 8 care service.

9 (d) (1) All enrollee grievances involving a disputed health care 10 service are eligible for review under the Independent Medical 11 Review System if the requirements of this article are met. If the 12 department finds that an enrollee grievance involving a disputed 13 health care service does not meet the requirements of this article 14 for review under the Independent Medical Review System, the 15 enrollee request for review shall be treated as a request for the 16 department to review the grievance pursuant to subdivision (b) of 17 Section 1368. All other enrollee grievances, including grievances 18 involving coverage decisions, remain eligible for review by the 19 department pursuant to subdivision (b) of Section 1368.

20 (2) In any case in which an enrollee or provider asserts that a 21 decision to deny, modify, or delay health care services was based, 22 in whole or in part, on consideration of medical necessity, the 23 department shall have the final authority to determine whether the 24 grievance is more properly resolved pursuant to an independent 25 medical review as provided under this article or pursuant to 26 subdivision (b) of Section 1368.

27 (3) The department shall be the final arbiter when there is a 28 question as to whether an enrollee grievance is a disputed health 29 care service or a coverage decision. The department shall establish 30 a process to complete an initial screening of an enrollee grievance. 31 If there appears to be any medical necessity issue, the grievance 32 shall be resolved pursuant to an independent medical review as 33 provided under this article or pursuant to subdivision (b) of Section 34 1368.

35 (e) Every health care service plan contract that is issued, 36 amended, renewed, or delivered in this state on or after January 37 1, 2000, shall, effective January 1, 2001, provide an enrollee with 38 the opportunity to seek an independent medical review whenever 39 health care services have been denied, modified, or delayed by the 40 plan, or by one of its contracting providers, if the decision was

1 based in whole or in part on a finding that the proposed health care 2 services are not medically necessary. For purposes of this article, 3 an enrollee may designate an agent to act on his or her behalf, as 4 described in paragraph (2) of subdivision (b) of Section 1368. The 5 provider may join with or otherwise assist the enrollee in seeking 6 an independent medical review, and may advocate on behalf of 7 the enrollee.

8 (f) Medi-Cal beneficiaries enrolled in a health care service plan 9 shall not be excluded from participation. Medicare beneficiaries 10 enrolled in a health care service plan shall not be excluded unless 11 expressly preempted by federal law. Reviews of cases for Medi-Cal 12 enrollees shall be conducted in accordance with statutes and 13 regulations for the Medi-Cal program.

14 (g) The department may seek to integrate the quality of care 15 and consumer protection provisions, including remedies, of the 16 Independent Medical Review System with related dispute 17 resolution procedures of other health care agency programs, 18 including the Medicare and Medi-Cal programs, in a way that 19 minimizes the potential for duplication, conflict, and added costs. 20 Nothing in this subdivision shall be construed to limit any rights

21 conferred upon enrollees under this chapter.

22 (h) The independent medical review process authorized by this 23 article is in addition to any other procedures or remedies that may 24 be available.

25 (i) No later than January 1, 2001, every health care service plan 26 shall prominently display in every plan member handbook or 27 relevant informational brochure, in every plan contract, on enrollee 28 evidence of coverage forms, on copies of plan procedures for 29 resolving grievances, on letters of denials issued by either the plan 30 or its contracting organization, on the grievance forms required 31 under Section 1368, and on all written responses to grievances, 32 information concerning the right of an enrollee to request an 33 independent medical review in cases where the enrollee believes 34 that health care services have been improperly denied, modified, 35 or delayed by the plan, or by one of its contracting providers.

36 (j) An enrollee may apply to the department for an independent 37 medical review when all of the following conditions are met:

38 (1) (A) The enrollee’s provider has recommended a health care 39 service as medically necessary, or

1 (B) The enrollee has received urgent care or emergency services 2 that a provider determined was medically necessary, or

3 (C) The enrollee, in the absence of a provider recommendation 4 under subparagraph (A) or the receipt of urgent care or emergency 5 services by a provider under subparagraph (B), has been seen by 6 an in-plan provider for the diagnosis or treatment of the medical 7 condition for which the enrollee seeks independent review. The 8 plan shall expedite access to an in-plan provider upon request of 9 an enrollee. The in-plan provider need not recommend the disputed

10 health care service as a condition for the enrollee to be eligible for 11 an independent review.

12 For purposes of this article, the enrollee's provider may be an 13 out-of-plan provider. However, the plan shall have no liability for 14 payment of services provided by an out-of-plan provider, except 15 as provided pursuant to subdivision (c) of Section 1374.34.

16 (2) The disputed health care service has been denied, modified, 17 or delayed by the plan, or by one of its contracting providers, based 18 in whole or in part on a decision that the health care service is not 19 medically necessary.

20 (3) The enrollee has filed a grievance with the plan or its 21 contracting provider pursuant to Section 1368, and the disputed 22 decision is upheld or the grievance remains unresolved after 30 23 days. The enrollee shall not be required to participate in the plan's 24 grievance process for more than 30 days. In the case of a grievance 25 that requires expedited review pursuant to Section 1368.01, the 26 enrollee shall not be required to participate in the plan's grievance 27 process for more than three days.

28 (k) *(1)* An enrollee may apply to the department for an 29 independent medical review of a decision to deny, modify, or delay 30 health care services, based in whole or in part on a finding that the 31 disputed health care services are not medically necessary, within 32 six months of any of the qualifying periods or events under 33 subdivision (j). The director may extend the application deadline 34 beyond six months if the circumstances of a case warrant the

35 extension.

(2) An enrollee or an enrollee's provider may request an line 37 expeditious medical review pursuant to Section 1374.31 if there line 38 is an imminent and serious threat to the health of the enrollee, line 39 including, but not limited to, serious pain, the potential loss of life, line 40 limb, or major bodily function, or the immediate and serious

(*l*) The enrollee shall pay no application or processing fees of any kind.

(m) As part of its notification to the enrollee regarding a disposition of the enrollee's grievance that denies, modifies, or delays health care services, the plan shall provide the enrollee with a one-page application form approved by the department, and an addressed envelope, which the enrollee may return to initiate an independent medical review. The plan shall include on the form any information required by the department to facilitate the completion of the independent medical review, such as the enrollee's diagnosis or condition, the nature of the disputed health care service sought by the enrollee, a means to identify the enrollee's case, and any other material information. The form shall also include the following:

(1) Notice that a decision not to participate in the independent medical review process may cause the enrollee to forfeit any statutory right to pursue legal action against the plan regarding the disputed health care service.

(2) A statement indicating the enrollee's consent to obtain any necessary medical records from the plan, any of its contracting providers, and any out-of-plan provider the enrollee may have consulted on the matter, to be signed by the enrollee.

(3) Notice of the enrollee's right to provide information or documentation, either directly or through the enrollee's provider, regarding any of the following:

(A) A provider recommendation indicating that the disputed health care service is medically necessary for the enrollee's medical condition.

(B) Medical information or justification that a disputed health care service, on an urgent care or emergency basis, was medically necessary for the enrollee's medical condition.

(C) Reasonable information supporting the enrollee's position that the disputed health care service is or was medically necessary

1 for the enrollee's medical condition, including all information 2 provided to the enrollee by the plan or any of its contracting 3 providers, still in the possession of the enrollee, concerning a plan 4 or provider decision regarding disputed health care services, and 5 a copy of any materials the enrollee submitted to the plan, still in 6 the possession of the enrollee, in support of the grievance, as well 7 as any additional material that the enrollee believes is relevant.

8 (n) Upon notice from the department that the health care service 9 plan's enrollee has applied for an independent medical review, the 10 plan or its contracting providers shall provide to the independent 11 medical review organization designated by the department a copy 12 of all of the following documents within three business days of 13 the plan's receipt of the department's notice of a request by an 14 enrollee for an independent review:

15 (1) (A) A copy of all of the enrollee's medical records in the 16 possession of the plan or its contracting providers relevant to each 17 of the following:

18 (i) The enrollee's medical condition.

19 (ii) The health care services being provided by the plan and its 20 contracting providers for the condition.

21 (iii) The disputed health care services requested by the enrollee 22 for the condition.

23 (B) Any newly developed or discovered relevant medical records 24 in the possession of the plan or its contracting providers after the 25 initial documents are provided to the independent medical review 26 organization shall be forwarded immediately to the independent 27 medical review organization. The plan shall concurrently provide 28 a copy of medical records required by this subparagraph to the 29 enrollee or the enrollee's provider, if authorized by the enrollee, 30 unless the offer of medical records is declined or otherwise 31 prohibited by law. The confidentiality of all medical record 32 information shall be maintained pursuant to applicable state and 33 federal laws.

34 (2) A copy of all information provided to the enrollee by the 35 plan and any of its contracting providers concerning plan and 36 provider decisions regarding the enrollee's condition and care, and 37 a copy of any materials the enrollee or the enrollee's provider 38 submitted to the plan and to the plan's contracting providers in 39 support of the enrollee's request for disputed health care services. 40 This documentation shall include the written response to the

1 enrollee’s grievance, required by paragraph (4) of subdivision (a) 2 of Section 1368. The confidentiality of any enrollee medical 3 information shall be maintained pursuant to applicable state and 4 federal laws.

5 (3) A copy of any other relevant documents or information used 6 by the plan or its contracting providers in determining whether 7 disputed health care services should have been provided, and any 8 statements by the plan and its contracting providers explaining the 9 reasons for the decision to deny, modify, or delay disputed health 10 care services on the basis of medical necessity. The plan shall 11 concurrently provide a copy of documents required by this 12 paragraph, except for any information found by the director to be 13 legally privileged information, to the enrollee and the enrollee’s 14 provider. The department and the independent medical review 15 organization shall maintain the confidentiality of any information 16 found by the director to be the proprietary information of the plan.

17 (o) This section shall become inoperative on July 1, 2015, and, 18 as of January 1, 2016, is repealed, unless a later enacted statute, 19 that becomes operative on or before January 1, 2016, deletes or 20 extends the dates on which it becomes inoperative and is repealed.

21 SEC. 3. Section 1374.30 of the Health and Safety Code, as line 22 added by Section 2 of Chapter 872 of the Statutes of 2012, is line 23 amended to read:

24 1374.30. (a) Commencing January 1, 2001, there is hereby line 25 established in the department the Independent Medical Review line 26 System.

27 (b) For the purposes of this chapter, “disputed health care 28 service” means any health care service eligible for coverage and 29 payment under a health care service plan contract that has been 30 denied, modified, or delayed by a decision of the plan, or by one 31 of its contracting providers, in whole or in part due to a finding 32 that the service is not medically necessary. A decision regarding 33 a disputed health care service relates to the practice of medicine 34 and is not a coverage decision. A disputed health care service does 35 not include services provided by a specialized health care service 36 plan, except to the extent that the service (1) involves the practice 37 of medicine, or (2) is provided pursuant to a contract with a health 38 care service plan that covers hospital, medical, or surgical benefits. 39 If a plan, or one of its contracting providers, issues a decision 40 denying, modifying, or delaying health care services, based in

1 whole or in part on a finding that the proposed health care services 2 are not a covered benefit under the contract that applies to the 3 enrollee, the statement of decision shall clearly specify the 4 provision in the contract that excludes that coverage.

5 (c) For the purposes of this chapter, “coverage decision” means 6 the approval or denial of health care services by a plan, or by one 7 of its contracting entities, substantially based on a finding that the 8 provision of a particular service is included or excluded as a 9 covered benefit under the terms and conditions of the health care 10 service plan contract. A “coverage decision” does not encompass 11 a plan or contracting provider decision regarding a disputed health 12 care service.

13 (d) (1) All enrollee grievances involving a disputed health care 14 service are eligible for review under the Independent Medical 15 Review System if the requirements of this article are met. If the 16 department finds that an enrollee grievance involving a disputed 17 health care service does not meet the requirements of this article 18 for review under the Independent Medical Review System, the 19 enrollee request for review shall be treated as a request for the

20 department to review the grievance pursuant to subdivision (b) of 21 Section 1368. All other enrollee grievances, including grievances 22 involving coverage decisions, remain eligible for review by the 23 department pursuant to subdivision (b) of Section 1368.

24 (2) In any case in which an enrollee or provider asserts that a 25 decision to deny, modify, or delay health care services was based, 26 in whole or in part, on consideration of medical necessity, the 27 department shall have the final authority to determine whether the 28 grievance is more properly resolved pursuant to an independent 29 medical review as provided under this article or pursuant to 30 subdivision (b) of Section 1368.

31 (3) The department shall be the final arbiter when there is a 32 question as to whether an enrollee grievance is a disputed health 33 care service or a coverage decision. The department shall establish 34 a process to complete an initial screening of an enrollee grievance. 35 If there appears to be any medical necessity issue, the grievance 36 shall be resolved pursuant to an independent medical review as 37 provided under this article or pursuant to subdivision (b) of Section 38 1368.

39 (e) Every health care service plan contract that is issued, 40 amended, renewed, or delivered in this state on or after January

1 1, 2000, shall provide an enrollee with the opportunity to seek an 2 independent medical review whenever health care services have 3 been denied, modified, or delayed by the plan, or by one of its 4 contracting providers, if the decision was based in whole or in part 5 on a finding that the proposed health care services are not medically 6 necessary. For purposes of this article, an enrollee may designate 7 an agent to act on his or her behalf, as described in paragraph (2) 8 of subdivision (b) of Section 1368. The provider may join with or 9 otherwise assist the enrollee in seeking an independent medical 10 review, and may advocate on behalf of the enrollee.

11 (f) Medi-Cal beneficiaries enrolled in a health care service plan 12 shall not be excluded from participation. Medicare beneficiaries 13 enrolled in a health care service plan shall not be excluded unless 14 expressly preempted by federal law. Reviews of cases for Medi-Cal 15 enrollees shall be conducted in accordance with statutes and 16 regulations for the Medi-Cal program.

17 (g) The department may seek to integrate the quality of care 18 and consumer protection provisions, including remedies, of the 19 Independent Medical Review System with related dispute 20 resolution procedures of other health care agency programs, 21 including the Medicare and Medi-Cal programs, in a way that 22 minimizes the potential for duplication, conflict, and added costs. 23 Nothing in this subdivision shall be construed to limit any rights

24 conferred upon enrollees under this chapter.

25 (h) The independent medical review process authorized by this 26 article is in addition to any other procedures or remedies that may 27 be available.

28 (i) Every health care service plan shall prominently display in 29 every plan member handbook or relevant informational brochure, 30 in every plan contract, on enrollee evidence of coverage forms, on 31 copies of plan procedures for resolving grievances, on letters of 32 denials issued by either the plan or its contracting organization, 33 on the grievance forms required under Section 1368, and on all 34 written responses to grievances, information concerning the right 35 of an enrollee to request an independent medical review in cases 36 where the enrollee believes that health care services have been 37 improperly denied, modified, or delayed by the plan, or by one of 38 its contracting providers.

39 (j) An enrollee may apply to the department for an independent 40 medical review when all of the following conditions are met:

1 (1) (A) The enrollee's provider has recommended a health care 2 service as medically necessary, or

3 (B) The enrollee has received urgent care or emergency services 4 that a provider determined was medically necessary, or

5 (C) The enrollee, in the absence of a provider recommendation 6 under subparagraph (A) or the receipt of urgent care or emergency 7 services by a provider under subparagraph (B), has been seen by 8 an in-plan provider for the diagnosis or treatment of the medical 9 condition for which the enrollee seeks independent review. The 10 plan shall expedite access to an in-plan provider upon request of 11 an enrollee. The in-plan provider need not recommend the disputed 12 health care service as a condition for the enrollee to be eligible for 13 an independent review.

14 For purposes of this article, the enrollee's provider may be an 15 out-of-plan provider. However, the plan shall have no liability for 16 payment of services provided by an out-of-plan provider, except 17 as provided pursuant to subdivision (c) of Section 1374.34.

18 (2) The disputed health care service has been denied, modified, 19 or delayed by the plan, or by one of its contracting providers, based 20 in whole or in part on a decision that the health care service is not 21 medically necessary.

22 (3) The enrollee has filed a grievance with the plan or its 23 contracting provider pursuant to Section 1368, and the disputed 24 decision is upheld or the grievance remains unresolved after 30 25 days. The enrollee shall not be required to participate in the plan's 26 grievance process for more than 30 days. In the case of a grievance 27 that requires expedited review pursuant to Section 1368.01, the 28 enrollee shall not be required to participate in the plan's grievance 29 process for more than three days.

30 (k) *(1)* An enrollee may apply to the department for an 31 independent medical review of a decision to deny, modify, or delay 32 health care services, based in whole or in part on a finding that the 33 disputed health care services are not medically necessary, within 34 six months of any of the qualifying periods or events under 35 subdivision (j). The director may extend the application deadline 36 beyond six months if the circumstances of a case warrant the 37 extension.

(2) An enrollee or an enrollee's provider may request an line 39 expeditious medical review pursuant to Section 1374.31 if there line 40 is an imminent and serious threat to the health of the enrollee,

(*l*) The enrollee shall pay no application or processing fees of any kind.

(m) As part of its notification to the enrollee regarding a disposition of the enrollee's grievance that denies, modifies, or delays health care services, the plan shall provide the enrollee with a one- or two-page application form approved by the department, and an addressed envelope, which the enrollee may return to initiate an independent medical review. The plan shall include on the form any information required by the department to facilitate the completion of the independent medical review, such as the enrollee's diagnosis or condition, the nature of the disputed health care service sought by the enrollee, a means to identify the enrollee's case, and any other material information. The form shall also include the following:

(1) Notice that a decision not to participate in the independent medical review process may cause the enrollee to forfeit any statutory right to pursue legal action against the plan regarding the disputed health care service.

(2) A statement indicating the enrollee's consent to obtain any necessary medical records from the plan, any of its contracting providers, and any out-of-plan provider the enrollee may have consulted on the matter, to be signed by the enrollee.

(3) Notice of the enrollee's right to provide information or documentation, either directly or through the enrollee's provider, regarding any of the following:

(A) A provider recommendation indicating that the disputed health care service is medically necessary for the enrollee's medical condition.

(B) Medical information or justification that a disputed health care service, on an urgent care or emergency basis, was medically necessary for the enrollee's medical condition.

(C) Reasonable information supporting the enrollee's position that the disputed health care service is or was medically necessary for the enrollee's medical condition, including all information provided to the enrollee by the plan or any of its contracting providers, still in the possession of the enrollee, concerning a plan or provider decision regarding disputed health care services, and a copy of any materials the enrollee submitted to the plan, still in the possession of the enrollee, in support of the grievance, as well as any additional material that the enrollee believes is relevant.

(4) A section designed to collect information on the enrollee's ethnicity, race, and primary language spoken that includes both of the following:

(A) A statement of intent indicating that the information is used for statistics only, in order to ensure that all enrollees get the best care possible.

(B) A statement indicating that providing this information is optional and will not affect the independent medical review process in any way.

(n) Upon notice from the department that the health care service plan's enrollee has applied for an independent medical review, the plan or its contracting providers shall provide to the independent medical review organization designated by the department a copy of all of the following documents within three business days of the plan's receipt of the department's notice of a request by an enrollee for an independent review:

(1) (A) A copy of all of the enrollee's medical records in the possession of the plan or its contracting providers relevant to each of the following:

(i) The enrollee's medical condition.

(ii) The health care services being provided by the plan and its contracting providers for the condition.

(iii) The disputed health care services requested by the enrollee for the condition.

(B) Any newly developed or discovered relevant medical records in the possession of the plan or its contracting providers after the initial documents are provided to the independent medical review organization shall be forwarded immediately to the independent medical review organization. The plan shall concurrently provide a copy of medical records required by this subparagraph to the enrollee or the enrollee's provider, if authorized by the enrollee,

1 unless the offer of medical records is declined or otherwise 2 prohibited by law. The confidentiality of all medical record 3 information shall be maintained pursuant to applicable state and 4 federal laws.

5 (2) A copy of all information provided to the enrollee by the 6 plan and any of its contracting providers concerning plan and 7 provider decisions regarding the enrollee's condition and care, and 8 a copy of any materials the enrollee or the enrollee's provider 9 submitted to the plan and to the plan's contracting providers in 10 support of the enrollee's request for disputed health care services. 11 This documentation shall include the written response to the 12 enrollee's grievance, required by paragraph (4) of subdivision (a) 13 of Section 1368. The confidentiality of any enrollee medical 14 information shall be maintained pursuant to applicable state and 15 federal laws.

16 (3) A copy of any other relevant documents or information used 17 by the plan or its contracting providers in determining whether 18 disputed health care services should have been provided, and any 19 statements by the plan and its contracting providers explaining the 20 reasons for the decision to deny, modify, or delay disputed health 21 care services on the basis of medical necessity. The plan shall 22 concurrently provide a copy of documents required by this

23 paragraph, except for any information found by the director to be 24 legally privileged information, to the enrollee and the enrollee's 25 provider. The department and the independent medical review 26 organization shall maintain the confidentiality of any information 27 found by the director to be the proprietary information of the plan.

28 (o) This section shall become operative on July 1, 2015.

29 SEC. 4. Section 10123.193 is added to the Insurance Code, to line 30 read:

31 10123.193. (a) Every health insurer that provides coverage line 32 for outpatient prescription drug benefits shall provide coverage line 33 for all medically necessary outpatient prescription drugs, except line 34 as described in this section.

35 (1) "Outpatient prescription drugs" are self-administered drugs 36 approved by the federal Food and Drug Administration for sale to 37 the public through retail or mail order pharmacies that require 38 prescriptions and are not provided for use on an inpatient basis.

39 (2) Coverage for outpatient prescription drugs shall include 40 coverage for disposable devices that are medically necessary for

1 the administration of a covered outpatient prescription drug, 2 including spacers and inhalers for the administration of aerosol 3 outpatient prescription drugs, and syringes for self-injectible 4 outpatient prescription drugs that are not dispensed in prefilled 5 syringes. For purposes of this paragraph, the term “disposable” 6 includes devices that may be used more than once before disposal. 7 This section does not create an obligation for a plan to provide 8 coverage for a durable medical equipment benefit.

9 (b) Standards for an outpatient prescription drug benefit shall 10 be as follows:

11 (1) An outpatient prescription drug benefit offered by a health 12 insurer policy shall comply with the requirements of this part and 13 the regulations promulgated by the commissioner.

14 (2) All clinical aspects of a policy’s outpatient prescription drug 15 benefit shall be developed by qualified medical and pharmacy 16 professionals in accordance with good professional practice. The 17 insurer shall establish and document an internal process for ongoing 18 review by qualified medical and pharmacy professionals of the 19 clinical aspects of the outpatient prescription drug benefit, 20 including review of limitations and exclusions, and the safety, 21 efficacy, and utilization of outpatient prescription drugs, including 22 step therapy, if any.

23 (3) Insurers seeking to establish limitations or exclusions on an 24 outpatient prescription drug benefit shall do so consistent with 25 up-to-date evidence-based outcomes and current published, 26 peer-reviewed medical and pharmaceutical literature.

27 (4) A health insurance policy that provides coverage for 28 outpatient prescription drugs through a mail order pharmacy shall 29 have written policies and procedures documenting that the health 30 insurance policy’s mail order arrangements are in compliance with 31 the requirements of this part, and applicable California and federal 32 laws regarding pharmacists and pharmacy services. The mail order 33 pharmacy process shall conform effectively and efficiently with 34 an insurer’s processes for prior authorization for coverage of 35 medically necessary drugs as required by this part, and shall include 36 standards for timely delivery and a contingency mechanism for 37 providing the drug if a mail order provider fails to meet the delivery 38 standards.

39 (5) In reviewing copayments, coinsurance, deductibles, 40 limitations, or exclusions, the department’s approval or disapproval

1 may be based upon all relevant factors, including, but not limited 2 to, the following:

3 (A) The type and number of insureds affected.

4 (B) The clinical efficacy of the drug or drugs proposed to be 5 limited or excluded.

6 (C) The availability of therapeutic equivalents or other drugs 7 medically necessary for treatment of health conditions.

8 (D) The specific health insurance products to which the 9 copayment, coinsurance, deductible, limitation, or exclusion will 10 apply.

11 (E) The duration of the limitation or exclusion.

12 (F) The rationale for the copayment, coinsurance, deductible, 13 limitation or exclusion.

14 (G) The projected effect of the copayment, coinsurance, 15 deductible, limitation, or exclusion on the affordability and 16 accessibility of coverage.

17 (H) The projected comparative clinical effect, including any 18 potential risk of adverse health outcomes, based upon utilization 19 data and review of peer-reviewed professional literature.

20 (I) The overall copayment structure of the product, including 21 whether the copayment, coinsurance, or deductible contributes to 22 the overall out-of-pocket maximum for the product.

23 (J) Information regarding similar copayments, coinsurance 24 levels, deductibles, limitations, or exclusions previously approved 25 by the department.

26 (K) Evidence-based clinical studies and professional literature.

27 (L) The description of the copayment, coinsurance, deductible, 28 limitation, or exclusion as compared to other benefits and products 29 in the marketplace.

30 (M) Any other historical, statistical, or other information that 31 the submitting insurer considers pertinent to the request for 32 approval of the copayments, coinsurance level, deductibles, 33 limitation, or exclusion.

34 (c) Copayments, coinsurance and deductibles shall be consistent 35 with Sections 10112.28, 10112.29, and 10112.3.

36 (1) A policy’s outpatient prescription drug benefit shall provide 37 that if the pharmacy’s retail price for a prescription drug is less 38 than the applicable copayment amount, the insured shall not be 39 required to pay any more than the retail price.

(2) Proposed copayment structures or ranges, coinsurance, or deductibles submitted to the commissioner for approval shall be based upon a methodology that is fully described and documented, and that complies with the standards set forth in this section. A health insurer may use actual cost data on prescription drugs or, for contracted services or products, nationally recognized data sources used by the health insurer in developing the policy rates.

(3) A copayment or percentage coinsurance shall not exceed 50 percent of the cost to the insurer. A percentage coinsurance shall meet each of the following additional requirements:

(A) Have a maximum dollar amount cap on the percentage coinsurance that will be charged for an individual prescription.

(B) Apply towards an annual out-of-pocket maximum for the product.

(C) Apply towards an annual out-of-pocket maximum for the outpatient prescription drug benefit, if any.

(4) In addition to compliance with this subdivision, copayments and coinsurances shall comply with the standards identified in subdivision (b), including that they shall be reasonable so as to allow access to medically necessary outpatient prescription drugs, and the department's determination may be based on all relevant factors as provided in paragraph (5) of subdivision (b).

(5) As used in paragraph (3), the "cost to the insurer" means the actual cost incurred by the insurer or its contracting provider to acquire and dispense a covered outpatient prescription drug, without subtracting or otherwise considering any copayment or coinsurance amount to be paid by insureds. The cost to the insurer may include average cost calculations as described in this section, and shall include all discounts and other prospective cost and pricing arrangements, as applicable. Insurers shall account for any rebates and other retrospective cost and pricing arrangements for outpatient prescription drugs by verifying that the rebates and other retrospective cost and pricing arrangements for outpatient prescription drugs are applied by the insurer to reduce costs for the policyholders.

(d) Policies that provide coverage for outpatient prescription drug benefits may apply the following limitations:

(1) A policy may impose prior authorization requirements on outpatient prescription drug benefits, consistent with the requirements of this part and corresponding regulations.

(2) When there is more than one drug that is appropriate for the treatment of a medical condition, a policy may require step therapy. A policy that requires step therapy shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements of this part and regulations. In circumstances where an insured is changing policies, the new policy may not require the insured to repeat step therapy when that insured is already being treated for a medical condition by an outpatient prescription drug, provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition. Nothing in this section shall preclude the new policy from imposing a prior authorization requirement pursuant for the continued coverage of an outpatient prescription drug prescribed pursuant to step therapy imposed by the former policy, or preclude the prescribing provider from prescribing another drug covered by the new policy that is medically appropriate for the insured. Step therapy, including the expeditious process for exception and the instances when an insured is changing policies, shall be subject to subdivision (b). For purposes of this section, "step therapy" means a protocol that specifies the sequence in which different prescription drugs for a given medical condition that are medically appropriate for a particular patient are to be prescribed.

(3) A policy shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.

(A) A policy may limit the amount of the drug dispensed at any one time to a 30-day supply or, if the treatment is for less than 30 days, for the medically necessary amount of the drug.

(B) A policy may impose a requirement that maintenance drugs be dispensed in a two-month or greater supply.

(C) A policy may establish a mandatory mail order process for maintenance drugs when dispensed in a three-month supply or greater quantities, but shall not impose any fees or costs for mandatory mail order prescriptions other than the applicable copayment or coinsurance. A policy shall not require an insured to fill a prescription by mail if the prescribed drug is not available to be filled in that manner.

1 (D) For purposes of this section, “maintenance drugs” means 2 those outpatient prescription drugs that are prescribed for the 3 insured on a continual basis to treat a chronic condition.

4 (4) Policies may require an insured who is prescribed drugs for 5 smoking cessation to be enrolled in or to have completed a smoking 6 cessation program, if covered by the policy prior to or concurrent 7 with receiving the prescription drug.

8 (5) Other limitations that the department may approve pursuant 9 to this section.

10 (e) Policies that provide coverage for outpatient prescription 11 drug benefits are not required to provide coverage for prescription 12 drugs that meet the following conditions:

13 (1) When prescribed for cosmetic purposes. For purposes of 14 this section “cosmetic purposes” means solely for the purpose of 15 altering or affecting normal structures of the body to improve 16 appearance rather than function.

17 (2) When prescribed solely for the treatment of hair loss, sexual 18 dysfunction, athletic performance, anti-aging for cosmetic 19 purposes, and mental performance. Drugs for mental performance 20 shall not be excluded from coverage when they are used to treat 21 diagnosed mental illness or medical conditions affecting memory, 22 including, but not limited to, treatment of the conditions or 23 symptoms of dementia or Alzheimer’s disease.

24 (3) When prescribed solely for the purposes of losing weight, 25 except when medically necessary for the treatment of morbid 26 obesity. Policies may require insureds who are prescribed drugs 27 for morbid obesity to be enrolled in a comprehensive weight loss 28 program, if covered by the policy, for a reasonable period of time 29 prior to or concurrent with receiving the prescription drug.

30 (4) When prescribed solely for the purpose of shortening the 31 duration of the common cold.

32 (5) Drugs that are available over the counter. A policy shall not 33 exclude coverage of an entire class of prescription drugs when one 34 drug within that class becomes available over the counter. A policy 35 that seeks to exclude coverage for an entire class of drugs when 36 more than one drug within that class become available over the 37 counter shall first file a notice of material modification and obtain 38 the department’s prior approval in accordance with subdivision 39 (g).

40 (6) Replacement of lost or stolen drugs.

1 (7) Drugs when prescribed by noncontracting providers for 2 noncovered procedures that are not authorized by an insurer or a 3 provider except when coverage is otherwise required in the context 4 of emergency services.

5 (8) Other categories of prescription drugs approved by the 6 department pursuant to this section.

7 (f) A health insurer policy shall have written policies and 8 procedures for its outpatient prescription drug benefits and quality 9 assurance systems in place for the early identification and swift 10 correction of problems in the accessibility and availability of 11 outpatient prescription drug benefits. A contract between a health 12 insurer and a prescription drug benefit provider shall include 13 provisions, terms, and conditions sufficient to ensure that the 14 standards and requirements of this section are met.

15 (g) Any exclusion or limitation on an outpatient prescription 16 drug benefit that is not described in subdivision (d) or (e) shall not 17 be applied to a policy's outpatient prescription drug benefit unless 18 an insurer has filed a notice of material modification with the 19 department and received approval by order to apply the exclusion 20 or limitation. The order of approval may be issued subject to 21 specified terms and conditions, or for specified periods, as the 22 department may determine are necessary and appropriate. 23 Following issuance of an order approving an exclusion or 24 limitation, any other insurer may apply the same exclusion or 25 limitation to its outpatient prescription drug benefit if it files an 26 amendment with the department not less than 30 days prior to 27 implementation of the exclusion or limitation, represents that it is 28 exactly the same as that previously approved by order, provides 29 specific reference to the order number and date issued, and 30 addresses any specified terms and conditions upon that order, as 31 applicable.

32 SEC. 5. Section 10169 of the Insurance Code, as amended by line 33 Section 7 of Chapter 872 of the Statutes of 2012, is amended to line 34 read:

35 10169. (a) Commencing January 1, 2001, there is hereby line 36 established in the department the Independent Medical Review line 37 System.

38 (b) For the purposes of this chapter, "disputed health care 39 service" means any health care service eligible for coverage and 40 payment under a disability insurance contract that has been denied,

1 modified, or delayed by a decision of the insurer, or by one of its 2 contracting providers, in whole or in part due to a finding that the 3 service is not medically necessary. A decision regarding a disputed 4 health care service relates to the practice of medicine and is not a 5 coverage decision. A disputed health care service does not include 6 services provided by a group or individual policy of vision-only 7 or dental-only coverage, except to the extent that (1) the service 8 involves the practice of medicine, or (2) is provided pursuant to a 9 contract with a disability insurer that covers hospital, medical, or 10 surgical benefits. If an insurer, or one of its contracting providers, 11 issues a decision denying, modifying, or delaying health care 12 services, based in whole or in part on a finding that the proposed 13 health care services are not a covered benefit under the contract 14 that applies to the insured, the statement of decision shall clearly 15 specify the provision in the contract that excludes that coverage.

16 (c) For the purposes of this chapter, “coverage decision” means 17 the approval or denial of health care services by a disability insurer, 18 or by one of its contracting entities, substantially based on a finding 19 that the provision of a particular service is included or excluded 20 as a covered benefit under the terms and conditions of the disability 21 insurance contract. A coverage decision does not encompass a 22 disability insurer or contracting provider decision regarding a 23 disputed health care service.

24 (d) (1) All insured grievances involving a disputed health care 25 service are eligible for review under the Independent Medical 26 Review System if the requirements of this article are met. If the 27 department finds that an insured grievance involving a disputed 28 health care service does not meet the requirements of this article 29 for review under the Independent Medical Review System, the 30 insured request for review shall be treated as a request for the 31 department to review the grievance. All other insured grievances, 32 including grievances involving coverage decisions, remain eligible 33 for review by the department.

34 (2) In any case in which an insured or provider asserts that a 35 decision to deny, modify, or delay health care services was based, 36 in whole or in part, on consideration of medical necessity, the 37 department shall have the final authority to determine whether the 38 grievance is more properly resolved pursuant to an independent 39 medical review as provided under this article.

(3) The department shall be the final arbiter when there is a question as to whether an insured grievance is a disputed health care service or a coverage decision. The department shall establish a process to complete an initial screening of an insured grievance. If there appears to be any medical necessity issue, the grievance shall be resolved pursuant to an independent medical review as provided under this article.

(e) Every disability insurance contract that is issued, amended, renewed, or delivered in this state on or after January 1, 2000, shall, effective, January 1, 2001, provide an insured with the opportunity to seek an independent medical review whenever health care services have been denied, modified, or delayed by the insurer, or by one of its contracting providers, if the decision was based in whole or in part on a finding that the proposed health care services are not medically necessary. For purposes of this article, an insured may designate an agent to act on his or her behalf. The provider may join with or otherwise assist the insured in seeking an independent medical review, and may advocate on behalf of the insured.

(f) Medicare beneficiaries enrolled in Medicare + Choice products shall not be excluded unless expressly preempted by federal law.

(g) The department may seek to integrate the quality of care and consumer protection provisions, including remedies, of the Independent Medical Review System with related dispute resolution procedures of other health care agency programs, including the Medicare program, in a way that minimizes the potential for duplication, conflict, and added costs. Nothing in this subdivision shall be construed to limit any rights conferred upon insureds under this chapter.

(h) The independent medical review process authorized by this article is in addition to any other procedures or remedies that may be available.

(i) No later than January 1, 2001, every disability insurer shall prominently display in every insurer member handbook or relevant informational brochure, in every insurance contract, on insured evidence of coverage forms, on copies of insurer procedures for resolving grievances, on letters of denials issued by either the insurer or its contracting organization, and on all written responses to grievances, information concerning the right of an insured to

1 request an independent medical review in cases where the insured 2 believes that health care services have been improperly denied, 3 modified, or delayed by the insurer, or by one of its contracting 4 providers.

5 (j) An insured may apply to the department for an independent 6 medical review when all of the following conditions are met:

7 (1) (A) The insured's provider has recommended a health care 8 service as medically necessary, or

9 (B) The insured has received urgent care or emergency services 10 that a provider determined was medically necessary, or

11 (C) The insured, in the absence of a provider recommendation 12 under subparagraph (A) or the receipt of urgent care or emergency 13 services by a provider under subparagraph (B), has been seen by 14 a contracting provider for the diagnosis or treatment of the medical 15 condition for which the insured seeks independent review. The 16 insurer shall expedite access to a contracting provider upon request 17 of an insured. The contracting provider need not recommend the 18 disputed health care service as a condition for the insured to be 19 eligible for an independent review.

20 For purposes of this article, the insured's provider may be a 21 noncontracting provider. However, the insurer shall have no 22 liability for payment of services provided by a noncontracting 23 provider, except as provided pursuant to Section 10169.3.

24 (2) The disputed health care service has been denied, modified, 25 or delayed by the insurer, or by one of its contracting providers, 26 based in whole or in part on a decision that the health care service 27 is not medically necessary.

28 (3) The insured has filed a grievance with the insurer or its 29 contracting provider, and the disputed decision is upheld or the 30 grievance remains unresolved after 30 days. The insured shall not 31 be required to participate in the insurer's grievance process for 32 more than 30 days. In the case of a grievance that requires 33 expedited review, the insured shall not be required to participate 34 in the insurer's grievance process for more than three days.

35 (k) *(1)* An insured may apply to the department for an 36 independent medical review of a decision to deny, modify, or delay 37 health care services, based in whole or in part on a finding that the 38 disputed health care services are not medically necessary, within 39 six months of any of the qualifying periods or events under 40 subdivision (j). The commissioner may extend the application

1 deadline beyond six months if the circumstances of a case warrant 2 the extension.

(2) An insured or an insured's provider may request an line 4 expeditious medical review pursuant to Section 10169.1 if there line 5 is an imminent and serious threat to the health of the insured, line 6 including, but not limited to, serious pain, the potential loss of life, line 7 limb, or major bodily function, or the immediate and serious line 8 deterioration of the health of the insured. Whether or not the line 9 insured or the insured's provider requests an expeditious medical line 10 review, if the department determines that there is an imminent and line 11 serious threat to the health of the insured, then the department line 12 shall refer the decision for an expeditious medical review consistent line 13 with Section 10169.1 without completing the requirements of line 14 subdivision (m).

15 (*l*) The insured shall pay no application or processing fees of 16 any kind.

17 (m) As part of its notification to the insured regarding a 18 disposition of the insured's grievance that denies, modifies, or 19 delays health care services, the insurer shall provide the insured 20 with a one-page application form approved by the department, and 21 an addressed envelope, which the insured may return to initiate an 22 independent medical review. The insurer shall include on the form 23 any information required by the department to facilitate the 24 completion of the independent medical review, such as the 25 insured's diagnosis or condition, the nature of the disputed health 26 care service sought by the insured, a means to identify the insured's 27 case, and any other material information. The form shall also 28 include the following:

29 (1) Notice that a decision not to participate in the independent 30 review process may cause the insured to forfeit any statutory right 31 to pursue legal action against the insurer regarding the disputed 32 health care service.

33 (2) A statement indicating the insured's consent to obtain any 34 necessary medical records from the insurer, any of its contracting 35 providers, and any noncontracting provider the insured may have 36 consulted on the matter, to be signed by the insured.

37 (3) Notice of the insured's right to provide information or 38 documentation, either directly or through the insured's provider, 39 regarding any of the following:

(A) A provider recommendation indicating that the disputed health care service is medically necessary for the insured's medical condition.

(B) Medical information or justification that a disputed health care service, on an urgent care or emergency basis, was medically necessary for the insured's medical condition.

(C) Reasonable information supporting the insured's position that the disputed health care service is or was medically necessary for the insured's medical condition, including all information provided to the insured by the insurer or any of its contracting providers, still in the possession of the insured, concerning an insurer or provider decision regarding disputed health care services, and a copy of any materials the insured submitted to the insurer, still in the possession of the insured, in support of the grievance, as well as any additional material that the insured believes is relevant.

(n) Upon notice from the department that the insured has applied for an independent medical review, the insurer or its contracting providers, shall provide to the independent medical review organization designated by the department a copy of all of the following documents within three business days of the insurer's receipt of the department's notice of a request by an insured for an independent review:

(1) (A) A copy of all of the insured's medical records in the possession of the insurer or its contracting providers relevant to each of the following:

(i) The insured's medical condition.

(ii) The health care services being provided by the insurer and its contracting providers for the condition.

(iii) The disputed health care services requested by the insured for the condition.

(B) Any newly developed or discovered relevant medical records in the possession of the insurer or its contracting providers after the initial documents are provided to the independent medical review organization shall be forwarded immediately to the independent medical review organization. The insurer shall concurrently provide a copy of medical records required by this subparagraph to the insured or the insured's provider, if authorized by the insured, unless the offer of medical records is declined or otherwise prohibited by law. The confidentiality of all medical

1 record information shall be maintained pursuant to applicable state 2 and federal laws.

3 (2) A copy of all information provided to the insured by the 4 insurer and any of its contracting providers concerning insurer and 5 provider decisions regarding the insured's condition and care, and 6 a copy of any materials the insured or the insured's provider 7 submitted to the insurer and to the insurer's contracting providers 8 in support of the insured's request for disputed health care services. 9 This documentation shall include the written response to the 10 insured's grievance. The confidentiality of any insured medical 11 information shall be maintained pursuant to applicable state and 12 federal laws.

13 (3) A copy of any other relevant documents or information used 14 by the insurer or its contracting providers in determining whether 15 disputed health care services should have been provided, and any 16 statements by the insurer and its contracting providers explaining 17 the reasons for the decision to deny, modify, or delay disputed 18 health care services on the basis of medical necessity. The insurer 19 shall concurrently provide a copy of documents required by this 20 paragraph, except for any information found by the commissioner 21 to be legally privileged information, to the insured and the insured's 22 provider. The department and the independent medical review 23 organization shall maintain the confidentiality of any information 24 found by the commissioner to be the proprietary information of 25 the insurer.

26 (o) This section shall become inoperative on July 1, 2015, and, 27 as of January 1, 2016, is repealed, unless a later enacted statute, 28 that becomes operative on or before January 1, 2016, deletes or 29 extends the dates on which it becomes inoperative and is repealed.

30 SEC. 6. Section 10169 of the Insurance Code, as added by line 31 Section 8 of Chapter 872 of the Statutes of 2012, is amended to line 32 read:

33 10169. (a) Commencing January 1, 2001, there is hereby line 34 established in the department the Independent Medical Review line 35 System.

36 (b) For the purposes of this chapter, "disputed health care 37 service" means any health care service eligible for coverage and 38 payment under a disability insurance contract that has been denied, 39 modified, or delayed by a decision of the insurer, or by one of its 40 contracting providers, in whole or in part due to a finding that the

1 service is not medically necessary. A decision regarding a disputed 2 health care service relates to the practice of medicine and is not a 3 coverage decision. A disputed health care service does not include 4 services provided by a group or individual policy of vision-only 5 or dental-only coverage, except to the extent that (1) the service 6 involves the practice of medicine, or (2) is provided pursuant to a 7 contract with a disability insurer that covers hospital, medical, or 8 surgical benefits. If an insurer, or one of its contracting providers, 9 issues a decision denying, modifying, or delaying health care 10 services, based in whole or in part on a finding that the proposed 11 health care services are not a covered benefit under the contract 12 that applies to the insured, the statement of decision shall clearly 13 specify the provision in the contract that excludes that coverage.

14 (c) For the purposes of this chapter, “coverage decision” means 15 the approval or denial of health care services by a disability insurer, 16 or by one of its contracting entities, substantially based on a finding 17 that the provision of a particular service is included or excluded 18 as a covered benefit under the terms and conditions of the disability 19 insurance contract. A coverage decision does not encompass a 20 disability insurer or contracting provider decision regarding a 21 disputed health care service.

22 (d) (1) All insured grievances involving a disputed health care 23 service are eligible for review under the Independent Medical 24 Review System if the requirements of this article are met. If the 25 department finds that an insured grievance involving a disputed 26 health care service does not meet the requirements of this article 27 for review under the Independent Medical Review System, the 28 insured request for review shall be treated as a request for the

29 department to review the grievance. All other insured grievances, 30 including grievances involving coverage decisions, remain eligible 31 for review by the department.

32 (2) In any case in which an insured or provider asserts that a 33 decision to deny, modify, or delay health care services was based, 34 in whole or in part, on consideration of medical necessity, the 35 department shall have the final authority to determine whether the 36 grievance is more properly resolved pursuant to an independent 37 medical review as provided under this article.

38 (3) The department shall be the final arbiter when there is a 39 question as to whether an insured grievance is a disputed health 40 care service or a coverage decision. The department shall establish

1 a process to complete an initial screening of an insured grievance. 2 If there appears to be any medical necessity issue, the grievance 3 shall be resolved pursuant to an independent medical review as 4 provided under this article.

5 (e) Every disability insurance contract that is issued, amended, 6 renewed, or delivered in this state on or after January 1, 2000, shall 7 provide an insured with the opportunity to seek an independent 8 medical review whenever health care services have been denied, 9 modified, or delayed by the insurer, or by one of its contracting 10 providers, if the decision was based in whole or in part on a finding 11 that the proposed health care services are not medically necessary. 12 For purposes of this article, an insured may designate an agent to 13 act on his or her behalf. The provider may join with or otherwise 14 assist the insured in seeking an independent medical review, and 15 may advocate on behalf of the insured.

16 (f) Medicare beneficiaries enrolled in Medicare + Choice 17 products shall not be excluded unless expressly preempted by 18 federal law.

19 (g) The department may seek to integrate the quality of care 20 and consumer protection provisions, including remedies, of the 21 Independent Medical Review System with related dispute 22 resolution procedures of other health care agency programs, 23 including the Medicare program, in a way that minimizes the 24 potential for duplication, conflict, and added costs. Nothing in this 25 subdivision shall be construed to limit any rights conferred upon 26 insureds under this chapter.

27 (h) The independent medical review process authorized by this 28 article is in addition to any other procedures or remedies that may 29 be available.

30 (i) Every disability insurer shall prominently display in every 31 insurer member handbook or relevant informational brochure, in 32 every insurance contract, on insured evidence of coverage forms, 33 on copies of insurer procedures for resolving grievances, on letters 34 of denials issued by either the insurer or its contracting 35 organization, and on all written responses to grievances, 36 information concerning the right of an insured to request an

37 independent medical review in cases where the insured believes 38 that health care services have been improperly denied, modified, 39 or delayed by the insurer, or by one of its contracting providers.

(j) An insured may apply to the department for an independent medical review when all of the following conditions are met:

(1) (A) The insured's provider has recommended a health care service as medically necessary, or

(B) The insured has received urgent care or emergency services that a provider determined was medically necessary, or

(C) The insured, in the absence of a provider recommendation under subparagraph (A) or the receipt of urgent care or emergency services by a provider under subparagraph (B), has been seen by a contracting provider for the diagnosis or treatment of the medical condition for which the insured seeks independent review. The insurer shall expedite access to a contracting provider upon request of an insured. The contracting provider need not recommend the disputed health care service as a condition for the insured to be eligible for an independent review.

For purposes of this article, the insured's provider may be a noncontracting provider. However, the insurer shall have no liability for payment of services provided by a noncontracting provider, except as provided pursuant to Section 10169.3.

(2) The disputed health care service has been denied, modified, or delayed by the insurer, or by one of its contracting providers, based in whole or in part on a decision that the health care service is not medically necessary.

(3) The insured has filed a grievance with the insurer or its contracting provider, and the disputed decision is upheld or the grievance remains unresolved after 30 days. The insured shall not be required to participate in the insurer's grievance process for more than 30 days. In the case of a grievance that requires expedited review, the insured shall not be required to participate in the insurer's grievance process for more than three days.

(k) *(1)* An insured may apply to the department for an independent medical review of a decision to deny, modify, or delay health care services, based in whole or in part on a finding that the disputed health care services are not medically necessary, within six months of any of the qualifying periods or events under subdivision (j). The commissioner may extend the application deadline beyond six months if the circumstances of a case warrant the extension.

(2) An insured or an insured's provider may request an line 40 expeditious medical review pursuant to Section 10169.1 if there

(*l*) The insured shall pay no application or processing fees of any kind.

(m) As part of its notification to the insured regarding a disposition of the insured's grievance that denies, modifies, or delays health care services, the insurer shall provide the insured with a one- or two-page application form approved by the department, and an addressed envelope, which the insured may return to initiate an independent medical review. The insurer shall include on the form any information required by the department to facilitate the completion of the independent medical review, such as the insured's diagnosis or condition, the nature of the disputed health care service sought by the insured, a means to identify the insured's case, and any other material information. The form shall also include the following:

(1) Notice that a decision not to participate in the independent review process may cause the insured to forfeit any statutory right to pursue legal action against the insurer regarding the disputed health care service.

(2) A statement indicating the insured's consent to obtain any necessary medical records from the insurer, any of its contracting providers, and any noncontracting provider the insured may have consulted on the matter, to be signed by the insured.

(3) Notice of the insured's right to provide information or documentation, either directly or through the insured's provider, regarding any of the following:

(A) A provider recommendation indicating that the disputed health care service is medically necessary for the insured's medical condition.

(B) Medical information or justification that a disputed health care service, on an urgent care or emergency basis, was medically necessary for the insured's medical condition.

(C) Reasonable information supporting the insured's position that the disputed health care service is or was medically necessary for the insured's medical condition, including all information provided to the insured by the insurer or any of its contracting providers, still in the possession of the insured, concerning an insurer or provider decision regarding disputed health care services, and a copy of any materials the insured submitted to the insurer, still in the possession of the insured, in support of the grievance, as well as any additional material that the insured believes is relevant.

(4) A section designed to collect information on the insured's ethnicity, race, and primary language spoken that includes both of the following:

(A) A statement of intent indicating that the information is used for statistics only, in order to ensure that all insureds get the best care possible.

(B) A statement indicating that providing this information is optional and will not affect the independent medical review process in any way.

(n) Upon notice from the department that the insured has applied for an independent medical review, the insurer or its contracting providers, shall provide to the independent medical review organization designated by the department a copy of all of the following documents within three business days of the insurer's receipt of the department's notice of a request by an insured for an independent review:

(1) (A) A copy of all of the insured's medical records in the possession of the insurer or its contracting providers relevant to each of the following:

(i) The insured's medical condition.

(ii) The health care services being provided by the insurer and its contracting providers for the condition.

(iii) The disputed health care services requested by the insured for the condition.

(B) Any newly developed or discovered relevant medical records in the possession of the insurer or its contracting providers after the initial documents are provided to the independent medical

review organization shall be forwarded immediately to the independent medical review organization. The insurer shall concurrently provide a copy of medical records required by this subparagraph to the insured or the insured's provider, if authorized by the insured, unless the offer of medical records is declined or otherwise prohibited by law. The confidentiality of all medical record information shall be maintained pursuant to applicable state and federal laws.

(2) A copy of all information provided to the insured by the insurer and any of its contracting providers concerning insurer and provider decisions regarding the insured's condition and care, and a copy of any materials the insured or the insured's provider submitted to the insurer and to the insurer's contracting providers in support of the insured's request for disputed health care services. This documentation shall include the written response to the insured's grievance. The confidentiality of any insured medical information shall be maintained pursuant to applicable state and federal laws.

19 (3) A copy of any other relevant documents or information used 20 by the insurer or its contracting providers in determining whether 21 disputed health care services should have been provided, and any 22 statements by the insurer and its contracting providers explaining 23 the reasons for the decision to deny, modify, or delay disputed 24 health care services on the basis of medical necessity. The insurer 25 shall concurrently provide a copy of documents required by this 26 paragraph, except for any information found by the commissioner 27 to be legally privileged information, to the insured and the insured's 28 provider. The department and the independent medical review 29 organization shall maintain the confidentiality of any information 30 found by the commissioner to be the proprietary information of 31 the insurer.

32 (o) This section shall become operative on July 1, 2015.

33 SEC. 7. No reimbursement is required by this act pursuant to line 34 Section 6 of Article XIIIB of the California Constitution because line 35 the only costs that may be incurred by a local agency or school line 36 district will be incurred because this act creates a new crime or line 37 infraction, eliminates a crime or infraction, or changes the penalty line 38 for a crime or infraction, within the meaning of Section 17556 of line 39 the Government Code, or changes the definition of a crime within

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