ASSEMBLY BILL No. 889

Introduced by Assembly Member Frazier

February 22, 2013

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:

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

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

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

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

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

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

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

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

as spacers and inhalers for the administration of aerosol outpatient prescription drugs, and syringes for self-injectible outpatient prescription drugs that are not dispensed in prefilled syringes. For purposes of this paragraph, the term "disposable" includes devices that may be used more than once before disposal. This section does not create an obligation for a plan to provide coverage for a durable medical equipment benefit.

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

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

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

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

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

providing the drug if a mail order provider fails to meet the delivery standards.

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

(A) The type and number of enrollees affected.

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

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

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

(E) The duration of the limitation or exclusion.

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

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

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

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

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

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

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

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

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

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

(2) Proposed copayment structures or ranges, coinsurance, or deductibles submitted to the director 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 plan may use actual cost data on prescription drugs or, for contracted services or products, nationally recognized data sources used by the plan in developing the contract rates.

(3) A copayment or percentage coinsurance shall not exceed 50 percent of the cost to the plan. 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 at subdivision (e), 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 (e).

(5) As used in paragraph (3), the "cost to the plan" means the actual cost incurred by the plan 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 enrollees. The cost to the plan may include average cost calculations as described in this section, and shall include all discounts and other prospective cost and pricing arrangements, as applicable. Plans 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 plan to reduce costs for the plan's subscribers.

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

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

(2) When there is more than one drug that is appropriate for the treatment of a medical condition, a plan may require step therapy. A plan 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 chapter and regulations. In circumstances where an enrollee is changing plans, the new plan may not require the enrollee to repeat step therapy when that enrollee 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 enrollee's condition. Nothing in this section shall preclude the new plan from imposing a prior authorization requirement pursuant to Section 1367.24 for the continued coverage of an outpatient prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. Step therapy, including the expeditious process for exception and the instances when an enrollee is changing plans, shall be subject to subdivision (e). 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 plan 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 plan 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 plan may impose a requirement that maintenance drugs be dispensed in a two-month or greater supply.

(C) A plan 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 plan shall not require an enrollee to fill a prescription by mail if the prescribed drug is not available to be filled in that manner.

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

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

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

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

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

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

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

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

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

one drug within that class becomes available over the counter. A plan that seeks to exclude coverage for an entire class of drugs when more than one drug within that class become available over the counter shall first file a notice of material modification and obtain the department's prior approval in accordance with this section.

(6) Replacement of lost or stolen drugs.

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

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

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

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

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

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

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

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

~~(2) Different limitations, including caps on benefits.~~

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

~~(4) Different packages negotiated between purchasers and plans.~~

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

~~(6) Current and past practices.~~

~~(e) The department shall develop a regulation outlining the 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.~~

~~(f)~~

(k) Nothing in subdivision (b) or (c) shall permit a plan to limit prescription drug benefits provided in a manner that is inconsistent 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 authorize a plan that contracts with the State Department of Health Services to provide services to Medi-Cal beneficiaries or with the Managed Risk Medical Insurance Board to provide services to enrollees of the Healthy Families Program to provide coverage for prescription drugs that are not required pursuant to those programs

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

~~(h)~~

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

~~(i)~~

(n) The department shall periodically review its regulations developed pursuant to this section.

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

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

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

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

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

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

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

(3) The department shall be the final arbiter when there is a question as to whether an enrollee grievance is a disputed health care service or a coverage decision. The department shall establish a process to complete an initial screening of an enrollee 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 or pursuant to subdivision (b) of Section 1368.

(e) Every health care service plan contract that is issued, amended, renewed, or delivered in this state on or after January 1, 2000, shall, effective January 1, 2001, provide an enrollee with the opportunity to seek an independent medical review whenever health care services have been denied, modified, or delayed by the plan, 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 enrollee may designate an agent to act on his or her behalf, as described in paragraph (2) of subdivision (b) of Section 1368. The provider may join with or otherwise assist the enrollee in seeking an independent medical review, and may advocate on behalf of the enrollee.

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

(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 and Medi-Cal programs, 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 enrollees 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 health care service plan shall prominently display in every plan member handbook or relevant informational brochure, in every plan contract, on enrollee evidence of coverage forms, on copies of plan procedures for resolving grievances, on letters of denials issued by either the plan or its contracting organization, on the grievance forms required under Section 1368, and on all written responses to grievances, information concerning the right of an enrollee to request an independent medical review in cases where the enrollee believes that health care services have been improperly denied, modified, or delayed by the plan, or by one of its contracting providers.

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

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

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

(C) The enrollee, 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 an in-plan provider for the diagnosis or treatment of the medical condition for which the enrollee seeks independent review. The plan shall expedite access to an in-plan provider upon request of an enrollee. The in-plan provider need not recommend the disputed health care service as a condition for the enrollee to be eligible for an independent review.

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

(2) The disputed health care service has been denied, modified, or delayed by the plan, 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 enrollee has filed a grievance with the plan or its contracting provider pursuant to Section 1368, and the disputed decision is upheld or the grievance remains unresolved after 30 days. The enrollee shall not be required to participate in the plan's grievance process for more than 30 days. In the case of a grievance that requires expedited review pursuant to Section 1368.01, the enrollee shall not be required to participate in the plan's grievance process for more than three days.

(k) *(1)* An enrollee 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 director may extend the application deadline beyond six months if the circumstances of a case warrant the extension.

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

deterioration of the health of the enrollee. Whether or not the enrollee or the enrollee's provider requests an expeditious medical review, if the department determines that there is an imminent and serious threat to the health of the enrollee, the department shall refer the decision for an expeditious medical review consistent with Section 1374.31 without completing the requirements of subdivision (m).

(*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

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.

(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, 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 enrollee by the plan and any of its contracting providers concerning plan and provider decisions regarding the enrollee's condition and care, and a copy of any materials the enrollee or the enrollee's provider submitted to the plan and to the plan's contracting providers in support of the enrollee's request for disputed health care services. This documentation shall include the written response to the

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

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

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

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

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

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

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

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

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

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

(3) The department shall be the final arbiter when there is a question as to whether an enrollee grievance is a disputed health care service or a coverage decision. The department shall establish a process to complete an initial screening of an enrollee 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 or pursuant to subdivision (b) of Section 1368.

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

1, 2000, shall provide an enrollee with the opportunity to seek an independent medical review whenever health care services have been denied, modified, or delayed by the plan, 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 enrollee may designate an agent to act on his or her behalf, as described in paragraph (2) of subdivision (b) of Section 1368. The provider may join with or otherwise assist the enrollee in seeking an independent medical review, and may advocate on behalf of the enrollee.

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

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

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

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

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

(C) The enrollee, 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 an in-plan provider for the diagnosis or treatment of the medical condition for which the enrollee seeks independent review. The plan shall expedite access to an in-plan provider upon request of an enrollee. The in-plan provider need not recommend the disputed health care service as a condition for the enrollee to be eligible for an independent review.

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

(2) The disputed health care service has been denied, modified, or delayed by the plan, 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 enrollee has filed a grievance with the plan or its contracting provider pursuant to Section 1368, and the disputed decision is upheld or the grievance remains unresolved after 30 days. The enrollee shall not be required to participate in the plan's grievance process for more than 30 days. In the case of a grievance that requires expedited review pursuant to Section 1368.01, the enrollee shall not be required to participate in the plan's grievance process for more than three days.

(k) *(1)* An enrollee 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 director may extend the application deadline beyond six months if the circumstances of a case warrant the extension.

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

including, but not limited to, serious pain, the potential loss of life, limb, or major bodily function, or the immediate and serious deterioration of the health of the enrollee. Whether or not the enrollee or the enrollee's provider requests an expeditious medical review, if the department determines that there is an imminent and serious threat to the health of the enrollee, the department shall refer the decision for an expeditious medical review consistent with Section 1374.31 without completing the requirements of subdivision (m).

(*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,

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 enrollee by the plan and any of its contracting providers concerning plan and provider decisions regarding the enrollee's condition and care, and a copy of any materials the enrollee or the enrollee's provider submitted to the plan and to the plan's contracting providers in support of the enrollee's request for disputed health care services. This documentation shall include the written response to the enrollee's grievance, required by paragraph (4) of subdivision (a) of Section 1368. The confidentiality of any enrollee medical information shall be maintained pursuant to applicable state and federal laws.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) The type and number of insureds affected.

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

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

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

(E) The duration of the limitation or exclusion.

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

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

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

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

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

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

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

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

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

(1) A policy's outpatient prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment amount, the insured shall not be 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.

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

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

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

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

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

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

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

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

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

(6) Replacement of lost or stolen drugs.

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

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

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

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

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

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

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

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

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

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

(2) In any case in which an insured or provider asserts that a decision to deny, modify, or delay health care services was based, in whole or in part, on consideration of medical necessity, the department shall have the final authority to determine whether the grievance is more properly resolved pursuant to an independent 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

request an independent medical review in cases where the insured believes that health care services have been improperly denied, modified, 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 expeditious medical review pursuant to Section 10169.1 if there is an imminent and serious threat to the health of the insured, including, but not limited to, serious pain, the potential loss of life, limb, or major bodily function, or the immediate and serious deterioration of the health of the insured. Whether or not the insured or the insured's provider requests an expeditious medical review, if the department determines that there is an imminent and serious threat to the health of the insured, then the department shall refer the decision for an expeditious medical review consistent with Section 10169.1 without completing the requirements of subdivision (m).

(*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-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.

(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.

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

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

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

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

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

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

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

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

(2) In any case in which an insured or provider asserts that a decision to deny, modify, or delay health care services was based, in whole or in part, on consideration of medical necessity, the department shall have the final authority to determine whether the grievance is more properly resolved pursuant to an independent 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 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) 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 request an independent medical review in cases where the insured believes that health care services have been improperly denied, modified, 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 expeditious medical review pursuant to Section 10169.1 if there

is an imminent and serious threat to the health of the insured, including, but not limited to, serious pain, the potential loss of life, limb, or major bodily function, or the immediate and serious deterioration of the health of the insured. Whether or not the insured or the insured's provider requests an expeditious medical review, if the department determines that there is an imminent and serious threat to the health of the insured, then the department shall refer the decision for an expeditious medical review consistent with Section 10169.1 without completing the requirements of subdivision (m).

(*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.

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

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

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

the meaning of Section 6 of Article XIII B of the California Constitution.

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