AMENDED IN ASSEMBLY APRIL 6, 2016

AMENDED IN ASSEMBLY MARCH 17, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

# ASSEMBLY BILL No. 2400

**Introduced by Assembly Member Nazarian**
***(Coauthor: Assembly Member Roger Hernández)***

February 18, 2016

An act to amend Sections 1367.24, 1368, 1368.01, and 1374.30 of the Health and Safety Code, and to amend Sections 10123.191 and 10169 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2400, as amended, Nazarian. Prescription drug coverage: prior authorization and external review.

Existing federal law requires a group health plan and a health insurance issuer offering group or individual health insurance coverage to provide for a coverage appeals process, which includes both an internal review and an external review process, that applies if an enrollee receives an adverse benefit determination for a drug that is included on the health plan's formulary drug list.

For plan years commencing on or after January 1, 2016, existing federal law requires a health plan providing essential health benefits to have procedures in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing provider to request and gain access to clinically appropriate nonformulary drugs within certain timeframes, and have an external review if the initial request is denied by the plan.

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 and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plans to establish and maintain a grievance system approved by the department under which enrollees may submit grievances to the plan and requires plans to resolve those grievances within 30 days, except as specified. Existing law requires individual, small group, and large group health care service plans and health insurers that provide prescription drug coverage to comply with the external exception request review process required by federal law for nonformulary drugs.

The bill would specify that for nonformulary drugs, an external exception request may be filed in lieu of filing a grievance with the health care service plan or health insurer following an adverse benefit determination. With respect to formulary drugs, the bill would require the grievance system established by the plan or an insurer's internal grievance process to require a plan or insurer that provides coverage for outpatient prescription drugs to resolve grievances or complaints that involve the disapproval of a request for a formulary drug within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist.

The bill would make other conforming changes to implement these changes.

Because a willful violation of these requirements by a health care service plan 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 1367.24 of the Health and Safety Code is amended to read:

1367.24. (a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process

by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, to its prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02. Any health plan that is required to maintain an external exception request review process pursuant to subdivision (k) shall indicate in the notice required under this subdivision that the enrollee may file, in lieu of filing a grievance with the plan pursuant to Section 1368, a grievance seeking an external exception request review. An enrollee shall not be required to file a grievance with the plan or its contracting provider pursuant to Section 1368 if a plan disapproves a request to obtain authorization for a nonformulary drug under subdivision (a). If a plan disapproves a request to obtain authorization for a nonformulary drug and the enrollee files a grievance with the plan pursuant to Section 1368, the plan shall treat that request as a request to obtain an external exception request review.

(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.

(d) The process described in subdivision (a) by which enrollees may obtain medically necessary nonformulary drugs, including

specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.

(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:

(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

(3) Any plan arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the plan to encourage formulary compliance or otherwise manage prescription drug benefits.

(f) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the performance of the plan in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the plan as part of its report issued pursuant to Section 1380.

(g) The director shall not publicly disclose any information reviewed pursuant to this section that is determined by the director to be confidential pursuant to state law.

(h) For purposes of this section, “authorization” means approval by the health care service plan to provide payment for the prescription drug.

(i) Nonformulary prescription drugs shall include any drug for which an enrollee's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation or in cases in which the drug has been excluded in the plan contract pursuant to Section 1342.7.

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that a health care service plan furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

(k) For any individual, small group, or large health plan contracts, a health care service plan's process described in subdivision (a) shall comply with the request for exception and external exception request review processes described in subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts as described in subdivision (*l*).

(*l*) "Medi-Cal managed care health care service plan contract" means any entity that enters into a contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(m) Nothing in this section shall be construed to affect an enrollee's or subscriber's eligibility to submit a grievance to the department for review under Section 1368 or to apply to the department for an independent medical review under Section 1370.4, or Article 5.55 (commencing with Section 1374.30) of this chapter.

SEC. 2. Section 1368 of the Health and Safety Code is amended to read:

1368. (a) Every plan shall do all of the following:

(1) Establish and maintain a grievance system approved by the department under which enrollees may submit their grievances to the plan. Each system shall provide reasonable procedures in accordance with department regulations that shall ensure adequate

consideration of enrollee grievances and rectification when appropriate.

(2) Inform its subscribers and enrollees upon enrollment in the plan and annually thereafter of the procedure for processing and resolving grievances. The information shall include the location and telephone number where grievances may be submitted.

(3) Provide forms for grievances to be given to subscribers and enrollees who wish to register written grievances. The forms used by plans licensed pursuant to Section 1353 shall be approved by the director in advance as to format.

(4) (A) Provide for a written acknowledgment within five calendar days of the receipt of a grievance, except as noted in subparagraph (B). The acknowledgment shall advise the complainant of the following:

(i) That the grievance has been received.

(ii) The date of receipt.

(iii) The name of the plan representative and the telephone number and address of the plan representative who may be contacted about the grievance.

(B) (i) Grievances received by telephone, by facsimile, by email, or online through the plan's Internet Web site pursuant to Section 1368.015, that are not coverage disputes, disputed health care services involving medical necessity, or experimental or investigational treatment and that are resolved by the next business day following receipt are exempt from the requirements of subparagraph (A) and paragraph (5). The plan shall maintain a log of all these grievances. The log shall be periodically reviewed by the plan and shall include the following information for each complaint:

(I) The date of the call.

(II) The name of the complainant.

(III) The complainant's member identification number.

(IV) The nature of the grievance.

(V) The nature of the resolution.

(VI) The name of the plan representative who took the call and resolved the grievance.

(ii) For health plan contracts in the individual, small group, or large group markets, a health care service plan's response to grievances subject to Section 1367.24 shall also comply with subdivision (c) of Section 156.122 of Title 45 of the Code of

Federal Regulations. This paragraph shall not apply to Medi-Cal managed care health care service plan contracts or any entity that enters into a contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(5) Provide subscribers and enrollees with written responses to grievances, with a clear and concise explanation of the reasons for the plan's response. For grievances involving the delay, denial, or modification of health care services, the plan response shall describe the criteria used and the clinical reasons for its decision, including all criteria and clinical reasons related to medical necessity. If a plan, or one of its contracting providers, issues a decision delaying, denying, or modifying 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 decision shall clearly specify the provisions in the contract that exclude that coverage.

(6) For grievances involving the cancellation, rescission, or nonrenewal of a health care service plan contract, the health care service plan shall continue to provide coverage to the enrollee or subscriber under the terms of the health care service plan contract until a final determination of the enrollee's or subscriber's request for review has been made by the health care service plan or the director pursuant to Section 1365 and this section. This paragraph shall not apply if the health care service plan cancels or fails to renew the enrollee's or subscriber's health care service plan contract for nonpayment of premiums pursuant to paragraph (1) of subdivision (a) of Section 1365.

(7) Keep in its files all copies of grievances, and the responses thereto, for a period of five years.

(b) (1) (A) After completing the grievance process described in subdivision (a), participating in the process for at least 30 days, or completing the external exception request review process described in subdivision (k) of Section 1367.24, a subscriber or enrollee may submit the grievance or external exception request review decision to the department for review. In any case under the grievance process determined by the department to be a case involving an imminent and serious threat to the health of the

patient, including, but not limited to, severe pain, the potential loss of life, limb, or major bodily function, cancellations, rescissions, or the nonrenewal of a health care service plan contract, or in any other case when the department determines that an earlier review is warranted, a subscriber or enrollee shall not be required to complete the grievance process or to participate in the process for at least 30 days before submitting a grievance to the department for review.

(B) A grievance or external exception request review decision may be submitted to the department for review and resolution prior to any arbitration.

(C) Notwithstanding subparagraphs (A) and (B), the department may refer any grievance or external exception request review decision that does not pertain to compliance with this chapter to the State Department of Public Health, the California Department of Aging, the federal Centers for Medicare and Medicaid Services, or any other appropriate governmental entity for investigation and resolution.

(2) If the subscriber or enrollee is a minor, or is incompetent or incapacitated, the parent, guardian, conservator, relative, or other designee of the subscriber or enrollee, as appropriate, may submit the grievance or external exception request review decision to the department as the agent of the subscriber or enrollee. Further, a provider may join with, or otherwise assist, a subscriber or enrollee, or the agent, to submit the grievance or external exception request review decision to the department. In addition, following submission of the grievance or external exception request review decision to the department, the subscriber or enrollee, or the agent, may authorize the provider to assist, including advocating on behalf of the subscriber or enrollee. For purposes of this section, a "relative" includes the parent, stepparent, spouse, adult son or daughter, grandparent, brother, sister, uncle, or aunt of the subscriber or enrollee.

(3) The department shall review the written documents submitted with the subscriber's or the enrollee's request for review, or submitted by the agent on behalf of the subscriber or enrollee. The department may ask for additional information, and may hold an informal meeting with the involved parties, including providers who have joined in submitting the grievance or external exception request review decision or who are otherwise assisting or

advocating on behalf of the subscriber or enrollee. If after reviewing the record, the department concludes that the grievance or external exception request review decision, in whole or in part, is eligible for review under the independent medical review system established pursuant to Article 5.55 (commencing with Section 1374.30), the department shall immediately notify the subscriber or enrollee, or agent, of that option and shall, if requested orally or in writing, assist the subscriber or enrollee in participating in the independent medical review system.

(4) If after reviewing the record of a grievance or external exception request review decision, the department concludes that a health care service eligible for coverage and payment under a health care service plan contract has been delayed, denied, or modified by a plan, or by one of its contracting providers, in whole or in part due to a determination that the service is not medically necessary, and that determination was not communicated to the enrollee in writing along with a notice of the enrollee's potential right to participate in the independent medical review system, as required by this chapter, the director shall, by order, assess administrative penalties. A proceeding for the issuance of an order assessing administrative penalties shall be subject to appropriate notice of, and the opportunity for, a hearing with regard to the person affected in accordance with Section 1397. The administrative penalties shall not be deemed an exclusive remedy available to the director. These penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45.

(5) The department shall send a written notice of the final disposition of the grievance or external exception request review decision, and the reasons therefor, to the subscriber or enrollee, the agent, to any provider that has joined with or is otherwise assisting the subscriber or enrollee, and to the plan, within 30 calendar days of receipt of the request for review unless the director, in his or her discretion, determines that additional time is reasonably necessary to fully and fairly evaluate the relevant grievance or external exception request review decision. In any case not eligible for the independent medical review system established pursuant to Article 5.55 (commencing with Section 1374.30), the department's written notice shall include, at a minimum, the following:

(A) A summary of its findings and the reasons why the department found the plan to be, or not to be, in compliance with any applicable laws, regulations, or orders of the director.

(B) A discussion of the department's contact with any medical provider, or any other independent expert relied on by the department, along with a summary of the views and qualifications of that provider or expert.

(C) If the enrollee's grievance or external exception request review decision is sustained in whole or in part, information about any corrective action taken.

(6) In any department review of a grievance or external exception request review decision involving a disputed health care service, as defined in subdivision (b) of Section 1374.30, that is not eligible for the independent medical review system established pursuant to Article 5.55 (commencing with Section 1374.30), in which the department finds that the plan has delayed, denied, or modified health care services that are medically necessary, based on the specific medical circumstances of the enrollee, and those services are a covered benefit under the terms and conditions of the health care service plan contract, the department's written notice shall do either of the following:

(A) Order the plan to promptly offer and provide those health care services to the enrollee.

(B) Order the plan to promptly reimburse the enrollee for any reasonable costs associated with urgent care or emergency services, or other extraordinary and compelling health care services, when the department finds that the enrollee's decision to secure those services outside of the plan network was reasonable under the circumstances.

The department's order shall be binding on the plan.

(7) Distribution of the written notice shall not be deemed a waiver of any exemption or privilege under existing law, including, but not limited to, Section 6254.5 of the Government Code, for any information in connection with and including the written notice, nor shall any person employed or in any way retained by the department be required to testify as to that information or notice.

(8) The director shall establish and maintain a system of aging of grievances that are pending and unresolved for 30 days or more

that shall include a brief explanation of the reasons each grievance is pending and unresolved for 30 days or more.

(9) A subscriber or enrollee, or the agent acting on behalf of a subscriber or enrollee, may also request voluntary mediation with the plan prior to exercising the right to submit a grievance or external exception request review decision to the department. The use of mediation services shall not preclude the right to submit a grievance or external exception request review decision to the department upon completion of mediation. In order to initiate mediation, the subscriber or enrollee, or the agent acting on behalf of the subscriber or enrollee, and the plan shall voluntarily agree to mediation. Expenses for mediation shall be borne equally by both sides. The department shall have no administrative or enforcement responsibilities in connection with the voluntary mediation process authorized by this paragraph.

(c) The plan's grievance system shall include a system of aging of grievances that are pending and unresolved for 30 days or more. The plan shall provide a quarterly report to the director of grievances pending and unresolved for 30 or more days with separate categories of grievances for Medicare enrollees and Medi-Cal enrollees. The plan shall include with the report a brief explanation of the reasons each grievance is pending and unresolved for 30 days or more. The plan may include the following statement in the quarterly report that is made available to the public by the director:

> "Under Medicare and Medi-Cal law, Medicare enrollees and Medi-Cal enrollees each have separate avenues of appeal that are not available to other enrollees. Therefore, grievances pending and unresolved may reflect enrollees pursuing their Medicare or Medi-Cal appeal rights."

If requested by a plan, the director shall include this statement in a written report made available to the public and prepared by the director that describes or compares grievances that are pending and unresolved with the plan for 30 days or more. Additionally, the director shall, if requested by a plan, append to that written report a brief explanation, provided in writing by the plan, of the reasons why grievances described in that written report are pending and unresolved for 30 days or more. The director shall not be

required to include a statement or append a brief explanation to a written report that the director is required to prepare under this chapter, including Sections 1380 and 1397.5.

(d) Subject to subparagraph (C) of paragraph (1) of subdivision (b), the grievance or resolution procedures authorized by this section shall be in addition to any other procedures that may be available to any person, and failure to pursue, exhaust, or engage in the procedures described in this section shall not preclude the use of any other remedy provided by law.

(e) Nothing in this section shall be construed to allow the submission to the department of any provider grievance under this section. However, as part of a provider's duty to advocate for medically appropriate health care for his or her patients pursuant to Sections 510 and 2056 of the Business and Professions Code, nothing in this subdivision shall be construed to prohibit a provider from contacting and informing the department about any concerns he or she has regarding compliance with or enforcement of this chapter.

(f) To the extent required by Section 2719 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-19) and any subsequent rules or regulations, there shall be an independent external review pursuant to the standards required by the United States Secretary of Health and Human Services of a health care service plan's cancellation, rescission, or nonrenewal of an enrollee's or subscriber's coverage.

SEC. 3. Section 1368.01 of the Health and Safety Code is amended to read:

1368.01. (a) The grievance system shall require the plan to resolve grievances within 30 days, except as provided in subdivisions (c) and (d).

(b) The grievance system shall include a requirement for expedited plan review of grievances for cases involving an imminent and serious threat to the health of the patient, including, but not limited to, severe pain, potential loss of life, limb, or major bodily function. When the plan has notice of a case requiring expedited review, the grievance system shall require the plan to immediately inform enrollees and subscribers in writing of their right to notify the department of the grievance. The grievance system shall also require the plan to provide enrollees, subscribers, and the department with a written statement on the disposition or

pending status of the grievance no later than three days from receipt of the grievance, except as provided in subdivision (c). Paragraph (4) of subdivision (a) of Section 1368 shall not apply to grievances handled pursuant to this section.

(c) A health care service plan contract in the individual, small group, or large group markets that provides coverage for outpatient prescription drugs shall comply with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts or any entity that enters into a contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(d) The grievance system shall require a health care service plan that provides coverage for outpatient prescription drugs to resolve grievances within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, if the original request was an authorization for a formulary drug that requires prior authorization by the plan. For purposes of this subdivision, "exigent circumstances" shall have the same meaning as set forth in Section 1367.241.

SEC. 4. Section 1374.30 of the Health and Safety Code 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.~~ *necessary, or*

(B) The enrollee has received urgent care or emergency services that a provider determined was medically ~~necessary.~~ *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) Either of the following:

(A) 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 subdivision (b) of Section 1368.01, the enrollee shall not be required to participate in the plan's grievance process for more than three days. In the case of a grievance that requires expedited review pursuant to subdivision (d) of Section 1368.01, the enrollee shall not be required to participate in the plan's grievance process for more than 72 hours, or more than 24 hours if exigent circumstances exist.

(B) The enrollee has filed for an external exception request review decision with the plan or its contracting provider pursuant

to subdivision (k) of Section 1367.24, and the disputed decision is upheld or the external review remains unresolved after 72 hours, or after 24 hours if exigent circumstances exist.

(k) 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.

(*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. 5. Section 10123.191 of the Insurance Code is amended to read:

10123.191. (a) Notwithstanding any other law, on and after January 1, 2013, a health insurer that provides coverage for prescription drugs shall utilize and accept only the prior authorization form developed pursuant to subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs.

(b) (1) If a health insurer or a contracted physician group fails to respond within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request from a prescribing provider, the prior authorization request shall be deemed to have been granted.

(2) A health insurer's internal grievance process shall require a health insurer that provides coverage for outpatient prescription drugs to resolve grievances within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, if the original request was an authorization for a formulary drug that requires prior authorization by the health insurer.

(c) On or before January 1, 2017, the department and the Department of Managed Health Care shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health insurer shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health insurer.

(3) The completed form may also be electronically submitted from the prescribing provider to the health insurer.

(4) The department and the Department of Managed Health Care shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Managed Health Care, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for the pharmacy or medical drug benefit by a health insurer.

(2) A contracted physician group uses its own internal prior authorization process rather than the health insurer's prior authorization process for the health insurer's insureds.

(3) A contracted physician group is delegated a utilization management function by the health insurer concerning any prescription drug, regardless of the delegation of financial risk.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health insurer's group or individual policy.

(h) (1) A health insurer shall maintain a process for an external exception request review that complies with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

(2) An insured shall not be required to file a complaint with the health insurer or its contracting provider pursuant to its internal grievance process if a health insurer disapproves a request to obtain authorization for a nonformulary drug under subdivision (i). If a health insurer disapproves a request to obtain authorization for a nonformulary drug and the insured files a complaint with the health insurer, the health insurer shall treat that as a request to obtain an external exception request review.

(i) For an individual, small group, or large group health insurance policy, a health insurer that provides coverage for outpatient prescription drugs shall comply with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

(j) Nothing in this section shall be construed to affect an insured's or policyholder's eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).

(k) For purposes of this section:

(1) "Prescribing provider" shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.

(2) "Exigent circumstances" exist when an insured is suffering from a health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function or when an insured is undergoing a current course of treatment using a nonformulary drug.

(3) "Completed prior authorization request" means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

SEC. 6. Section 10169 of the Insurance Code, as added by Section 19 of Chapter 348 of the Statutes of 2015, 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 when the insured believes that health care services have been improperly denied, modified, or delayed by the insurer, or by one of its contracting providers. The department's telephone number, 1-800-927-4357, and Internet Web site, www.insurance.ca.gov, shall also be displayed.

(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) Either of the following:

(A) 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. In the case of a grievance that requires expedited review pursuant to paragraph (2) of subdivision (b) of Section 10123.191, the insured shall not be required to participate in the insured's grievance process for more than 72 hours, or more than 24 hours if exigent circumstances exist.

(B) The insured has filed for an external exception request review decision with the insurer or its contracting provider pursuant to subdivision (h) of Section 10123.191, and the disputed decision is upheld or the external review remains unresolved after 72 hours, or after 24 hours if exigent circumstances exist.

(k) 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.

(*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.

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.

O