

ASSEMBLY BILL

No. 2400

Introduced by Assembly Member Nazarian

February 18, 2016

An act to amend Sections 1367.24, 1367.241, 1367.244, 1368, 1368.01, and 1374.30 of the Health and Safety Code, and to amend Sections 10123.191, 10123.197, and 10169 of, and to add Section 10123.190 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2400, as introduced, 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 process required by federal law for nonformulary drugs.

This bill would require those plans and insurers to also comply with that external exception request process for formulary drugs that require prior authorization by the plan or health insurer. The bill would specify that, for both nonformulary and formulary drugs, the external exception process is in lieu of the health care service plan’s grievance process and the health insurer’s internal review process following an adverse benefit determination.

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:

1 SECTION 1. Section 1367.24 of the Health and Safety Code
2 is amended to read:
3 1367.24. (a) (1) Every health care service plan that provides
4 prescription drug benefits shall maintain an expeditious process,
5 *as described in this subdivision, by which enrollees, enrollees’*
6 *designees, or* prescribing providers may *request and* obtain
7 authorization for a medically necessary nonformulary prescription
8 drug. ~~On or before July 1, 1999, every health care service plan that~~
9 ~~provides prescription drug benefits shall file with the department~~
10 ~~a description of its process, including timelines, for responding to~~

1 authorization requests for nonformulary drugs. Any changes to
2 this process shall be filed with the department pursuant to Section
3 1352. Each drugs and medically necessary formulary prescription
4 drugs that require prior authorization by the plan. The plan shall
5 provide that the enrollee, the enrollee's designee, or the enrollee's
6 prescribing provider may seek a prior authorization for a
7 prescription drug under this subdivision.

8 (2) Each plan shall respond to a prior authorization request
9 within 72 hours following receipt of the prior authorization request.
10 A plan that grants a prior authorization request under this
11 paragraph shall provide coverage of the prescription drug for the
12 duration of the prescription, including refills.

13 (3) Each plan shall provide that a prior authorization may be
14 obtained within 24 hours if an enrollee is suffering from a health
15 condition that may seriously jeopardize the enrollee's life, health,
16 or ability to regain maximum function or if an enrollee is
17 undergoing a current course of treatment using a nonformulary
18 drug. A plan that grants a prior authorization request under this
19 paragraph based on exigent circumstances shall provide coverage
20 of the prescription drug for the duration of the exigency.

21 (4) If a plan fails to respond within 72 hours for a prior
22 authorization request, or within 24 hours if exigent circumstances
23 exist, upon receipt of a completed prior authorization request, the
24 prior authorization request shall be deemed to have been granted.

25 (5) Each plan shall provide a written description of its most
26 current process, including timelines, the process described in
27 paragraph (1) to its prescribing providers. For purposes of this
28 section, a prescribing provider shall include a provider authorized
29 to write a prescription, pursuant to subdivision (a) of Section 4040
30 of the Business and Professions Code, to treat a medical condition
31 of an enrollee.

32 (b) If a plan disapproves a prior authorization request made
33 pursuant to subdivision (a), the plan shall maintain an expeditious
34 process to authorize an enrollee to obtain an external review.

35 (1) A determination on an external review shall be made no
36 later than 72 hours following receipt of the request, if the original
37 request was an authorization request under paragraph (2) of
38 subdivision (a), and no later than 24 hours following receipt of
39 the request, if the original request was an authorization request
40 under paragraph (3) of subdivision (a).

1 (2) *If an external review decision of a prior authorization*
 2 *request under paragraph (2) of subdivision (a) is granted, the plan*
 3 *shall provide coverage of the prescription drug for the duration*
 4 *of the prescription, including refills. If an external review decision*
 5 *of a prior authorization request under paragraph (3) of subdivision*
 6 *(a) is granted, the plan shall provide coverage of the prescription*
 7 *drug for the duration of the exigency.*

8 ~~(b)~~

9 (c) Any plan that disapproves a request made pursuant to
 10 subdivision (a) ~~by a prescribing provider to obtain authorization~~
 11 ~~for a nonformulary or formulary drug shall provide the reasons~~
 12 ~~for the disapproval in a notice provided to the enrollee. The notice~~
 13 ~~shall indicate that the enrollee may file a grievance with the plan~~
 14 ~~file, in lieu of filing a grievance with the plan, a request for an~~
 15 ~~external review pursuant to subdivision (b) if the enrollee objects~~
 16 ~~to the disapproval, including any alternative drug or treatment~~
 17 ~~offered by the plan. The notice shall comply with subdivision (b)~~
 18 ~~of Section 1368.02. Any health plan that is required to maintain~~
 19 ~~an external exception request review process pursuant to~~
 20 ~~subdivision (k) shall indicate in the notice required under this~~
 21 ~~subdivision that the enrollee may file a grievance seeking an~~
 22 ~~external exception request review. If a plan disapproves a request~~
 23 ~~made pursuant to subdivision (a), an enrollee shall not be required~~
 24 ~~to file a grievance with the plan or its contracting provider~~
 25 ~~pursuant to Section 1368.~~

26 ~~(e)~~

27 (d) The process described in ~~subdivision~~ subdivisions (a) and
 28 (b) by which enrollee's, enrollees' designees, and prescribing
 29 providers may obtain authorization for medically necessary
 30 nonformulary drugs shall not apply to a nonformulary drug that
 31 has been prescribed for an enrollee in conformance with the
 32 provisions of Section 1367.22.

33 ~~(e)~~

34 (e) The process described in ~~subdivision~~ subdivisions (a) and
 35 (b) by which enrollees may obtain medically necessary
 36 nonformulary ~~drugs, including specified timelines for responding~~
 37 ~~to prescribing provider authorization requests, drugs and formulary~~
 38 ~~drugs shall be described in evidence of coverage and disclosure~~
 39 ~~forms, as required by subdivision (a) of Section 1363, issued on~~
 40 ~~or after July 1, 1999. July 1, 2017.~~

1 ~~(e)~~

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

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

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

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

24 ~~(f)~~

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

32 ~~(g)~~

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

36 ~~(h)~~

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

40 ~~(i)~~

1 (j) Nonformulary prescription drugs shall include any drug for
2 which an enrollee's copayment or out-of-pocket costs are different
3 than the copayment for a formulary prescription drug, except as
4 otherwise provided by law or regulation or in cases in which the
5 drug has been excluded in the plan contract pursuant to Section
6 1342.7.

7 (j)

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

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

23 (l) *A health care service plan contract in the individual, small*
24 *group, and large group markets that provides coverage for*
25 *outpatient prescription drugs shall comply with this section. This*
26 *section shall not apply to Medi-Cal managed care health care*
27 *service plan contracts.*

28 (l)

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

35 (m)

36 (n) Nothing in this section shall be construed to affect an
37 enrollee's or subscriber's eligibility to submit a grievance to the
38 department for review under Section 1368 or to apply to the
39 department for an independent medical review under Section

1 1370.4, or Article 5.55 (commencing with Section 1374.30) of
2 this chapter.

3 SEC. 2. Section 1367.241 of the Health and Safety Code is
4 amended to read:

5 1367.241. (a) Notwithstanding any other law, on and after
6 January 1, 2013, a health care service plan that provides coverage
7 for prescription drugs shall accept only the prior authorization
8 form developed pursuant to subdivision ~~(e)~~; *(b)*, or an electronic
9 prior authorization process described in subdivision ~~(e)~~; *(d)*, when
10 requiring prior authorization for prescription drugs. This section
11 does not apply in the event that a physician or physician group has
12 been delegated the financial risk for prescription drugs by a health
13 care service plan and does not use a prior authorization process.
14 This section does not apply to a health care service plan, or to its
15 affiliated providers, if the health care service plan owns and
16 operates its pharmacies and does not use a prior authorization
17 process for prescription drugs.

18 ~~(b) If a health care service plan or a contracted physician group~~
19 ~~fails to respond within 72 hours for nonurgent requests, and within~~
20 ~~24 hours if exigent circumstances exist, upon receipt of a completed~~
21 ~~prior authorization request from a prescribing provider, the prior~~
22 ~~authorization request shall be deemed to have been granted. The~~
23 ~~requirements of this subdivision shall not apply to contracts entered~~
24 ~~into pursuant to Chapter 7 (commencing with Section 14000),~~
25 ~~Chapter 8 (commencing with Section 14200), or Chapter 8.75~~
26 ~~(commencing with Section 14591) of Part 3 of Division 9 of the~~
27 ~~Welfare and Institutions Code. Medi-Cal managed care health care~~
28 ~~service plans that contract under those chapters shall not be~~
29 ~~required to maintain an external exception request review as~~
30 ~~provided in Section 156.122 of Title 45 of the Code of Federal~~
31 ~~Regulations.~~

32 (e)

33 (b) On or before January 1, 2017, the department and the
34 Department of Insurance shall jointly develop a uniform prior
35 authorization form. Notwithstanding any other law, on and after
36 July 1, 2017, or six months after the form is completed pursuant
37 to this section, whichever is later, every prescribing provider shall
38 use that uniform prior authorization form, or an electronic prior
39 authorization process described in subdivision ~~(e)~~; *(d)*, to request
40 prior authorization for coverage of prescription drugs and every

1 health care service plan shall accept that form or electronic process
2 as sufficient to request prior authorization for prescription drugs.

3 ~~(d)~~

4 (c) The prior authorization form developed pursuant to
5 subdivision-~~(e)~~ (b) shall meet the following criteria:

6 (1) The form shall not exceed two pages.

7 (2) The form shall be made electronically available by the
8 department and the health care service plan.

9 (3) The completed form may also be electronically submitted
10 from the prescribing provider to the health care service plan.

11 (4) The department and the Department of Insurance shall
12 develop the form with input from interested parties from at least
13 one public meeting.

14 (5) The department and the Department of Insurance, in
15 development of the standardized form, shall take into consideration
16 the following:

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

20 (B) National standards pertaining to electronic prior
21 authorization.

22 ~~(e)~~

23 (d) A prescribing provider may use an electronic prior
24 authorization system utilizing the standardized form described in
25 subdivision-~~(e)~~ (b) or an electronic process developed specifically
26 for transmitting prior authorization information that meets the
27 National Council for Prescription Drug Programs' SCRIPT
28 standard for electronic prior authorization transactions.

29 ~~(f)~~

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

31 (1) A contracted physician group is delegated the financial risk
32 for prescription drugs by a health care service plan.

33 (2) A contracted physician group uses its own internal prior
34 authorization process rather than the health care service plan's
35 prior authorization process for plan enrollees.

36 (3) A contracted physician group is delegated a utilization
37 management function by the health care service plan concerning
38 any prescription drug, regardless of the delegation of financial
39 risk.

40 ~~(g)~~

1 (f) For prescription drugs, prior authorization requirements
2 described in subdivisions ~~(e)~~ (b) and ~~(e)~~ (d) apply regardless of
3 how that benefit is classified under the terms of the health plan’s
4 group or individual contract.

5 ~~(h)~~

6 (g) For purposes of this section:

7 (1) “Prescribing provider” shall include a provider authorized
8 to write a prescription, pursuant to subdivision (a) of Section 4040
9 of the Business and Professions Code, to treat a medical condition
10 of an enrollee.

11 ~~(2) “Exigent circumstances” exist when an enrollee is suffering
12 from a health condition that may seriously jeopardize the enrollee’s
13 life, health, or ability to regain maximum function or when an
14 enrollee is undergoing a current course of treatment using a
15 nonformulary drug.~~

16 ~~(3)~~

17 (2) “Completed prior authorization request” means a completed
18 uniform prior authorization form developed pursuant to subdivision
19 ~~(e)~~, (b), or a completed request submitted using an electronic prior
20 authorization system described in subdivision ~~(e)~~, (d), or, for
21 contracted physician groups described in subdivision ~~(f)~~, (e), the
22 process used by the contracted physician group.

23 SEC. 3. Section 1367.244 of the Health and Safety Code is
24 amended to read:

25 1367.244. (a) A request for an exception to a health care
26 service plan’s step therapy process for prescription drugs may be
27 submitted in the same manner as a request for prior authorization
28 for prescription drugs pursuant to Section ~~1367.241~~, 1367.24, and
29 shall be treated in the same manner, and shall be responded to by
30 the health care service plan in the same manner, as a request for
31 prior authorization for prescription drugs.

32 (b) The department and the Department of Insurance shall
33 include a provision for step therapy exception requests in the
34 uniform prior authorization form developed pursuant to subdivision
35 ~~(e)~~ (b) of Section 1367.241.

36 SEC. 4. Section 1368 of the Health and Safety Code is amended
37 to read:

38 1368. (a) Every plan shall do all of the following:

39 (1) Establish and maintain a grievance system approved by the
40 department under which enrollees may submit their grievances to

1 the plan. Each system shall provide reasonable procedures in
2 accordance with department regulations that shall ensure adequate
3 consideration of enrollee grievances and rectification when
4 appropriate.

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

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

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

- 17 (i) That the grievance has been received.
- 18 (ii) The date of receipt.
- 19 (iii) The name of the plan representative and the telephone
20 number and address of the plan representative who may be
21 contacted about the grievance.

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

- 32 ~~(i)~~
- 33 (i) The date of the call.
- 34 ~~(ii)~~
- 35 (ii) The name of the complainant.
- 36 ~~(iii)~~
- 37 (iii) The complainant's member identification number.
- 38 ~~(iv)~~
- 39 (iv) The nature of the grievance.
- 40 ~~(v)~~

1 (v) The nature of the resolution.

2 ~~(VI)~~

3 (vi) The name of the plan representative who took the call and
4 resolved the grievance.

5 ~~(ii) For health plan contracts in the individual, small group, or~~
6 ~~large group markets, a health care service plan's response to~~
7 ~~grievances subject to Section 1367.24 shall also comply with~~
8 ~~subdivision (c) of Section 156.122 of Title 45 of the Code of~~
9 ~~Federal Regulations. This paragraph shall not apply to Medi-Cal~~
10 ~~managed care health care service plan contracts or any entity that~~
11 ~~enters into a contract with the State Department of Health Care~~
12 ~~Services pursuant to Chapter 7 (commencing with Section 14000),~~
13 ~~Chapter 8 (commencing with Section 14200), or Chapter 8.75~~
14 ~~(commencing with Section 14591) of Part 3 of Division 9 of the~~
15 ~~Welfare and Institutions Code.~~

16 (5) Provide subscribers and enrollees with written responses to
17 grievances, with a clear and concise explanation of the reasons for
18 the plan's response. For grievances involving the delay, denial, or
19 modification of health care services, the plan response shall
20 describe the criteria used and the clinical reasons for its decision,
21 including all criteria and clinical reasons related to medical
22 necessity. If a plan, or one of its contracting providers, issues a
23 decision delaying, denying, or modifying health care services based
24 in whole or in part on a finding that the proposed health care
25 services are not a covered benefit under the contract that applies
26 to the enrollee, the decision shall clearly specify the provisions in
27 the contract that exclude that coverage.

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

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

1 (b) (1) (A) After either completing the grievance process
2 described in subdivision ~~(a)~~, or *(a)*, participating in the process for
3 at least 30 days, or *completing the external review process*
4 *described in subdivision (b) of Section 1367.24*, a subscriber or
5 enrollee may submit the grievance or *external review decision* to
6 the department for review. In any case *under the grievance process*
7 determined by the department to be a case involving an imminent
8 and serious threat to the health of the patient, including, but not
9 limited to, severe pain, the potential loss of life, limb, or major
10 bodily function, cancellations, rescissions, or the nonrenewal of a
11 health care service plan contract, or in any other case where the
12 department determines that an earlier review is warranted, a
13 subscriber or enrollee shall not be required to complete the
14 grievance process or to participate in the process for at least 30
15 days before submitting a grievance to the department for review.

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

18 (C) Notwithstanding subparagraphs (A) and (B), the department
19 may refer any *grievance or external review decision* that does not
20 pertain to compliance with this chapter to the State Department of
21 Public Health, the California Department of Aging, the federal
22 ~~Health Care Financing Administration~~, *Centers for Medicare and*
23 *Medicaid Services*, or any other appropriate governmental entity
24 for investigation and resolution.

25 (2) If the subscriber or enrollee is a minor, or is incompetent or
26 incapacitated, the parent, guardian, conservator, relative, or other
27 designee of the subscriber or enrollee, as appropriate, may submit
28 the *grievance or external review decision* to the department as the
29 agent of the subscriber or enrollee. Further, a provider may join
30 with, or otherwise assist, a subscriber or enrollee, or the agent, to
31 submit the *grievance or external review decision* to the department.
32 In addition, following submission of the *grievance or external*
33 *review decision* to the department, the subscriber or enrollee, or
34 the agent, may authorize the provider to assist, including
35 advocating on behalf of the subscriber or enrollee. For purposes
36 of this section, a “relative” includes the parent, stepparent, spouse,
37 adult son or daughter, grandparent, brother, sister, uncle, or aunt
38 of the subscriber or enrollee.

39 (3) The department shall review the written documents submitted
40 with the subscriber’s or the enrollee’s request for review, or

1 submitted by the agent on behalf of the subscriber or enrollee. The
2 department may ask for additional information, and may hold an
3 informal meeting with the involved parties, including providers
4 who have joined in submitting the grievance *or external review*
5 *decision* or who are otherwise assisting or advocating on behalf
6 of the subscriber or enrollee. If after reviewing the record, the
7 department concludes that the ~~grievance~~, *grievance or external*
8 *review decision*, in whole or in part, is eligible for review under
9 the independent medical review system established pursuant to
10 Article 5.55 (commencing with Section 1374.30), the department
11 shall immediately notify the subscriber or enrollee, or agent, of
12 that option and shall, if requested orally or in writing, assist the
13 subscriber or enrollee in participating in the independent medical
14 review system.

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

33 (5) The department shall send a written notice of the final
34 disposition of the ~~grievance~~, *grievance or external review decision*,
35 and the reasons therefor, to the subscriber or enrollee, the agent,
36 to any provider that has joined with or is otherwise assisting the
37 subscriber or enrollee, and to the plan, within 30 calendar days of
38 receipt of the request for review unless the director, in his or her
39 discretion, determines that additional time is reasonably necessary
40 to fully and fairly evaluate the relevant ~~grievance~~. *grievance or*

1 *external review decision*. In any case not eligible for the
 2 independent medical review system established pursuant to Article
 3 5.55 (commencing with Section 1374.30), the department’s written
 4 notice shall include, at a minimum, the following:

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

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

12 (C) If the enrollee’s grievance *or external review decision* is
 13 sustained in whole or in part, information about any corrective
 14 action taken.

15 (6) In any department review of a grievance *or external review*
 16 *decision* involving a disputed health care service, as defined in
 17 subdivision (b) of Section 1374.30, that is not eligible for the
 18 independent medical review system established pursuant to Article
 19 5.55 (commencing with Section 1374.30), in which the department
 20 finds that the plan has delayed, denied, or modified health care
 21 services that are medically necessary, based on the specific medical
 22 circumstances of the enrollee, and those services are a covered
 23 benefit under the terms and conditions of the health care service
 24 plan contract, the department’s written notice shall do either of
 25 the following:

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

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

34 The department’s order shall be binding on the plan.

35 (7) Distribution of the written notice shall not be deemed a
 36 waiver of any exemption or privilege under existing law, including,
 37 but not limited to, Section 6254.5 of the Government Code, for
 38 any information in connection with and including the written
 39 notice, nor shall any person employed or in any way retained by

1 the department be required to testify as to that information or
2 notice.

3 (8) The director shall establish and maintain a system of aging
4 of grievances that are pending and unresolved for 30 days or more
5 that shall include a brief explanation of the reasons each grievance
6 is pending and unresolved for 30 days or more.

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

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

29
30 "Under Medicare and Medi-Cal law, Medicare enrollees and
31 Medi-Cal enrollees each have separate avenues of appeal that
32 are not available to other enrollees. Therefore, grievances
33 pending and unresolved may reflect enrollees pursuing their
34 Medicare or Medi-Cal appeal rights."

35
36 If requested by a plan, the director shall include this statement in
37 a written report made available to the public and prepared by the
38 director that describes or compares grievances that are pending
39 and unresolved with the plan for 30 days or more. Additionally,
40 the director shall, if requested by a plan, append to that written

1 report a brief explanation, provided in writing by the plan, of the
 2 reasons why grievances described in that written report are pending
 3 and unresolved for 30 days or more. The director shall not be
 4 required to include a statement or append a brief explanation to a
 5 written report that the director is required to prepare under this
 6 chapter, including Sections 1380 and 1397.5.

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

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

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

29 SEC. 5. Section 1368.01 of the Health and Safety Code is
 30 amended to read:

31 1368.01. (a) The grievance system shall require the plan to
 32 resolve grievances within 30 days, ~~except as provided in~~
 33 ~~subdivision (e).~~ *days.*

34 (b) The grievance system shall include a requirement for
 35 expedited plan review of grievances for cases involving an
 36 imminent and serious threat to the health of the patient, including,
 37 but not limited to, severe pain, potential loss of life, limb, or major
 38 bodily function. When the plan has notice of a case requiring
 39 expedited review, the grievance system shall require the plan to
 40 immediately inform enrollees and subscribers in writing of their

1 right to notify the department of the grievance. The grievance
2 system shall also require the plan to provide enrollees, subscribers,
3 and the department with a written statement on the disposition or
4 pending status of the grievance no later than three days from receipt
5 of the grievance, except as provided in subdivision (e). *grievance.*
6 Paragraph (4) of subdivision (a) of Section 1368 shall not apply
7 to grievances handled pursuant to this section.

8 ~~(e) A health care service plan contract in the individual, small
9 group, or large group markets that provides coverage for outpatient
10 prescription drugs shall comply with subdivision (e) of Section
11 156.122 of Title 45 of the Code of Federal Regulations. This
12 subdivision shall not apply to Medi-Cal managed care health care
13 service plan contracts or any entity that enters into a contract with
14 the State Department of Health Care Services pursuant to Chapter
15 7 (commencing with Section 14000), Chapter 8 (commencing with
16 Section 14200), or Chapter 8.75 (commencing with Section 14591)
17 of Part 3 of Division 9 of the Welfare and Institutions Code.~~

18 SEC. 6. Section 1374.30 of the Health and Safety Code is
19 amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 (B) *The enrollee has filed for an external review decision with*
 27 *the plan or its contracting provider pursuant to subdivision (b) of*
 28 *Section 1367.24, and the disputed decision is upheld or the external*
 29 *review remains unresolved after 72 hours, or 24 hours if exigent*
 30 *circumstances exist.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (i) The enrollee’s medical condition.

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

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

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

36 (2) A copy of all information provided to the enrollee by the
37 plan and any of its contracting providers concerning plan and
38 provider decisions regarding the enrollee’s condition and care, and
39 a copy of any materials the enrollee or the enrollee’s provider
40 submitted to the plan and to the plan’s contracting providers in

1 support of the enrollee’s request for disputed health care services.
2 This documentation shall include the written response to the
3 enrollee’s grievance, required by paragraph (4) of subdivision (a)
4 of Section 1368. The confidentiality of any enrollee medical
5 information shall be maintained pursuant to applicable state and
6 federal laws.

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

19 ~~(e) This section shall become operative on July 1, 2015.~~

20 SEC. 7. Section 10123.190 is added to the Insurance Code,
21 immediately following Section 10123.19, to read:

22 10123.190. (a) (1) Every health insurer that provides
23 prescription drug benefits shall maintain an expeditious process,
24 as described in this subdivision, by which insureds, insureds’
25 designees, or prescribing providers may request and obtain
26 authorization for medically necessary nonformulary prescription
27 drugs and medically necessary formulary drugs that require prior
28 authorization by the health insurer. The health insurer shall provide
29 that the insured, the insured’s designee, or the insured’s prescribing
30 provider may seek a prior authorization for a prescription drug
31 under this subdivision.

32 (2) Each health insurer shall respond to a prior authorization
33 request within 72 hours following receipt of the prior authorization
34 request. A health insurer that grants a prior authorization request
35 under this paragraph shall provide coverage of the prescription
36 drug for the duration of the prescription, including refills.

37 (3) Each health insurer shall provide that a prior authorization
38 may be obtained within 24 hours if an insured is suffering from a
39 health condition that may seriously jeopardize the insured’s life,
40 health, or ability to regain maximum function or if an insured is

1 undergoing a current course of treatment using a nonformulary
2 drug. A health insurer that grants a prior authorization request
3 under this paragraph based on exigent circumstances shall provide
4 coverage of the prescription drug for the duration of the exigency.

5 (4) If a health insurer fails to respond within 72 hours for a prior
6 authorization request, or within 24 hours if exigent circumstances
7 exist, upon receipt of a completed prior authorization request, the
8 prior authorization request shall be deemed to have been granted.

9 (5) Each health insurer shall provide a written description of
10 the process described in paragraph (1) to its prescribing providers.
11 For purposes of this section, a prescribing provider shall include
12 a provider authorized to write a prescription, pursuant to
13 subdivision (a) of Section 4040 of the Business and Professions
14 Code, to treat a medical condition of an insured.

15 (b) If a health insurer disapproves a prior authorization request
16 made pursuant to subdivision (a), the health insurer shall maintain
17 an expeditious process to authorize an insured to obtain an external
18 review.

19 (1) A determination on an external review shall be made no
20 later than 72 hours following receipt of the request, if the original
21 request was an authorization request under paragraph (2) of
22 subdivision (a), and no later than 24 hours following receipt of the
23 request, if the original request was an authorization request under
24 paragraph (3) of subdivision (a).

25 (2) If an external review decision of a prior authorization request
26 under paragraph (2) of subdivision (a) is granted, the health insurer
27 shall provide coverage of the prescription drug for the duration of
28 the prescription, including refills. If an external review decision
29 of a prior authorization request under paragraph (3) of subdivision
30 (a) is granted, the health insurer shall provide coverage of the
31 prescription drug for the duration of the exigency.

32 (c) Any health insurer that disapproves a request made pursuant
33 to subdivision (a) to obtain authorization for a nonformulary or
34 formulary drug shall provide the reasons for the disapproval in a
35 notice provided to the insured. The notice shall indicate that the
36 insured may file, in lieu of filing a grievance with the health
37 insurer, a request for an external review pursuant to subdivision
38 (b) if the insured objects to the disapproval, including any
39 alternative drug or treatment offered by the health insurer. If a
40 health insurer disapproves a request made pursuant to subdivision

1 (a), an insured shall not be required to file a grievance with the
2 health insurer or its contracting provider pursuant the grievance
3 process established by the health insurer.

4 (d) The process described in subdivisions (a) and (b) by which
5 insureds may obtain medically necessary nonformulary and
6 formulary drugs shall be described in the evidence of coverage or
7 certificate of insurance issued by the health insurer on or after July
8 1, 2017.

9 (e) A health insurance policy in the individual, small group, and
10 large group markets that provides coverage for outpatient
11 prescription drugs shall comply with this section.

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

17 SEC. 8. Section 10123.191 of the Insurance Code is amended
18 to read:

19 10123.191. (a) Notwithstanding any other law, on and after
20 January 1, 2013, a health insurer that provides coverage for
21 prescription drugs shall utilize and accept only the prior
22 authorization form developed pursuant to subdivision ~~(e)~~, (b), or
23 an electronic prior authorization process described in subdivision
24 ~~(e)~~, (d), when requiring prior authorization for prescription drugs.

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

30 ~~(e)~~

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

1 process as sufficient to request prior authorization for prescription
2 drugs.

3 ~~(d)~~

4 (c) The prior authorization form developed pursuant to
5 subdivision-~~(e)~~ (b) shall meet the following criteria:

6 (1) The form shall not exceed two pages.

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

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

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

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

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

20 (B) National standards pertaining to electronic prior
21 authorization.

22 ~~(e)~~

23 (d) A prescribing provider may use an electronic prior
24 authorization system utilizing the standardized form described in
25 subdivision-~~(e)~~ (b) or an electronic process developed specifically
26 for transmitting prior authorization information that meets the
27 National Council for Prescription Drug Programs' SCRIPT
28 standard for electronic prior authorization transactions.

29 ~~(f)~~

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

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

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

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

39 ~~(g)~~

1 (f) For prescription drugs, prior authorization requirements
2 described in subdivisions ~~(e)~~ (b) and ~~(e)~~ (d) apply regardless of
3 how that benefit is classified under the terms of the health insurer’s
4 group or individual policy.

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

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

12 ~~(j)~~

13 (g) For purposes of this section:

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

18 ~~(2) “Exigent circumstances” exist when an insured is suffering
19 from a health condition that may seriously jeopardize the insured’s
20 life, health, or ability to regain maximum function or when an
21 insured is undergoing a current course of treatment using a
22 nonformulary drug.~~

23 ~~(3)~~

24 (2) “Completed prior authorization request” means a completed
25 uniform prior authorization form developed pursuant to subdivision
26 ~~(e)~~; (b), or a completed request submitted using an electronic prior
27 authorization system described in subdivision ~~(e)~~; (d), or, for
28 contracted physician groups described in subdivision ~~(f)~~; (e), the
29 process used by the contracted physician group.

30 SEC. 9. Section 10123.197 of the Insurance Code is amended
31 to read:

32 10123.197. (a) A request for an exception to a health insurer’s
33 step therapy process for prescription drugs may be submitted in
34 the same manner as a request for prior authorization for prescription
35 drugs pursuant to Section ~~10123.191~~, 10123.190 and shall be
36 treated in the same manner, and shall be responded to by the health
37 insurer in the same manner, as a request for prior authorization for
38 prescription drugs.

39 (b) The department and the Department of Managed Health
40 Care shall include a provision for step therapy exception requests

1 in the uniform prior authorization form developed pursuant to
2 subdivision ~~(e)~~ (b) of Section 10123.191.

3 SEC. 10. Section 10169 of the Insurance Code, as added by
4 Section 19 of Chapter 348 of the Statutes of 2015, is amended to
5 read:

6 10169. (a) Commencing January 1, 2001, there is hereby
7 established in the department the Independent Medical Review
8 System.

9 (b) For the purposes of this chapter, “disputed health care
10 service” means any health care service eligible for coverage and
11 payment under a disability insurance contract that has been denied,
12 modified, or delayed by a decision of the insurer, or by one of its
13 contracting providers, in whole or in part due to a finding that the
14 service is not medically necessary. A decision regarding a disputed
15 health care service relates to the practice of medicine and is not a
16 coverage decision. A disputed health care service does not include
17 services provided by a group or individual policy of vision-only
18 or dental-only coverage, except to the extent that (1) the service
19 involves the practice of medicine, or (2) is provided pursuant to a
20 contract with a disability insurer that covers hospital, medical, or
21 surgical benefits. If an insurer, or one of its contracting providers,
22 issues a decision denying, modifying, or delaying health care
23 services, based in whole or in part on a finding that the proposed
24 health care services are not a covered benefit under the contract
25 that applies to the insured, the statement of decision shall clearly
26 specify the provision in the contract that excludes that coverage.

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

35 (d) (1) All insured grievances involving a disputed health care
36 service are eligible for review under the Independent Medical
37 Review System if the requirements of this article are met. If the
38 department finds that an insured grievance involving a disputed
39 health care service does not meet the requirements of this article
40 for review under the Independent Medical Review System, the

1 insured request for review shall be treated as a request for the
2 department to review the grievance. All other insured grievances,
3 including grievances involving coverage decisions, remain eligible
4 for review by the department.

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

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

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

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

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

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

4 (i) Every disability insurer shall prominently display in every
5 insurer member handbook or relevant informational brochure, in
6 every insurance contract, on insured evidence of coverage forms,
7 on copies of insurer procedures for resolving grievances, on letters
8 of denials issued by either the insurer or its contracting
9 organization, and on all written responses to grievances,
10 information concerning the right of an insured to request an
11 independent medical review when the insured believes that health
12 care services have been improperly denied, modified, or delayed
13 by the insurer, or by one of its contracting providers. The
14 department's telephone number, 1-800-927-4357, and Internet
15 Web site, www.insurance.ca.gov, shall also be displayed.

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

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

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

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

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

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

39 (3) (A) The insured has filed a grievance with the insurer or its
40 contracting provider, and the disputed decision is upheld or the

1 grievance remains unresolved after 30 days. The insured shall not
2 be required to participate in the insurer's grievance process for
3 more than 30 days. In the case of a grievance that requires
4 expedited review, the insured shall not be required to participate
5 in the insurer's grievance process for more than three ~~days~~: *days*,
6 *or*

7 *(B) The insured has filed for an external review decision with*
8 *the insurer or its contracting provider pursuant to subdivision (b)*
9 *of Section 10123.190, and the disputed decision is upheld or the*
10 *external review remains unresolved after 72 hours, or 24 hours if*
11 *exigent circumstances exist.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

39 (i) The insured’s medical condition.

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

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

5 (B) Any newly developed or discovered relevant medical records
6 in the possession of the insurer or its contracting providers after
7 the initial documents are provided to the independent medical
8 review organization shall be forwarded immediately to the
9 independent medical review organization. The insurer shall
10 concurrently provide a copy of medical records required by this
11 subparagraph to the insured or the insured's provider, if authorized
12 by the insured, unless the offer of medical records is declined or
13 otherwise prohibited by law. The confidentiality of all medical
14 record information shall be maintained pursuant to applicable state
15 and federal laws.

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

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

39 ~~(e) This section shall become operative on January 1, 2017.~~

1 SEC. 11. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution because
3 the only costs that may be incurred by a local agency or school
4 district will be incurred because this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the penalty
6 for a crime or infraction, within the meaning of Section 17556 of
7 the Government Code, or changes the definition of a crime within
8 the meaning of Section 6 of Article XIII B of the California
9 Constitution.

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