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CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 339

**Introduced by Assembly Member Gordon
(Coauthor: Assembly Member Atkins)**

February 13, 2015

An act to amend Sections 1367.24 and 1367.205 of, and to add ~~Section 1342.71~~ *Sections 1342.71, 1367.41, and 1367.42* to, the Health and Safety Code, and to amend Section 10123.192 of, and to add Sections 10123.193 and 10123.201 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 339, as amended, Gordon. Health care coverage: outpatient prescription drugs.

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 also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or insurer that provides prescription drug

benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would ~~require~~ *require, with respect to* a nongrandfathered group health care service plan contract or health insurance policy that is offered, renewed, or amended on or after July 1, 2016, and a nongrandfathered individual health care service plan contract or health insurance policy that is offered, renewed, or amended on or after January 1, 2017, and that provides coverage for outpatient prescription drugs, ~~to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent. The bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed $\frac{1}{24}$ of the annual out-of-pocket limit applicable to individual coverage \$250, except as specified,~~ for a supply of up to 30 days. ~~The bill would require these cost sharing limitations for a plan contract or policy that is a high deductible health plan to apply only once an enrollee's or insured's deductible has been satisfied for the year. The bill would make these cost-sharing limits applicable only to covered outpatient prescription drugs that constitute essential health benefits, as defined. The bill would require a plan contract or policy to cover a single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are clinically equally or more effective, regimen for combination drug treatments that include antiretrovirals, as specified. The bill would prohibit, except as specified, a plan contract or policy from placing prescription medications that treat a specific condition on the more than 50% of drugs approved by the United States Food and Drug Administration that are in the same drug class into the 2 highest cost tiers of a drug formulary. The bill would require a plan contract or policy to use specified definitions for each tier of a drug formulary. The bill would make related findings and declarations.~~

This bill would require a health insurer that provides coverage for outpatient prescription drugs to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent, and, for an insurer, would require copayments,

coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable.

Existing law requires every health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug, and requires these plans to maintain specified information that is required to be made available to the Director of the Department of Managed Health Care upon request.

This bill would also impose these requirements on a health insurer that provides prescription drug benefits, as provided. The bill would require a plan or insurer to respond to authorization requests for nonformulary prescription drugs within specified timeframes. The bill would authorize ~~a plan or~~ an insurer to require step therapy, as defined, when more than one drug is appropriate for the treatment of a medical condition, subject to specified requirements. The bill would require ~~a plan or~~ an insurer that requires step therapy to have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements. The bill, with regard to ~~an enrollee or~~ insured changing ~~plans or~~ policies, would prohibit a new ~~plan or~~ insurer from requiring the enrollee or insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. The bill, except as specified, would require a plan or insurer that provides essential health benefits to allow an enrollee or insured to access his or her prescription drug benefits at an in-network retail pharmacy, and would authorize a plan or insurer to charge an enrollee or insured a different cost sharing for obtaining a covered drug at a retail pharmacy, and would require that cost-sharing amount to count towards the plan's or insurer's annual out-of-pocket limitation, as specified.

This bill would require a plan or insurer to maintain a pharmacy and therapeutics committee that is responsible for developing, maintaining, and overseeing any drug formulary list, as provided. The bill would require the committee to, among other things, evaluate and analyze treatment protocols and procedures related to the plan's or insurer's drug formulary at least annually.

Existing law requires the Department of Managed Health Care and the Department of Insurance to jointly develop a standard formulary template by January 1, 2017, and requires plans and insurers to use that

template to display formularies, as specified. Existing law requires the standard formulary template to include specified information.

This bill would require the standard formulary template to include additional specified information, including which medications are covered, including both generic and brand name.

Because a willful violation of the bill’s requirements relative to health care service plans would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1342.71 is added to the Health and Safety
2 Code, to read:

3 1342.71. (a) *The Legislature hereby finds and declares all of*
4 *the following:*

5 (1) *The federal Patient Protection and Affordable Care Act, its*
6 *implementing regulations and guidance, and related state law*
7 *prohibit discrimination based on a person’s expected length of*
8 *life, present or predicted disability, degree of medical dependency,*
9 *quality of life, or other health conditions, including benefit designs*
10 *that have the effect of discouraging the enrollment of individuals*
11 *with significant health needs.*

12 (2) *The Legislature intends to build on existing state and federal*
13 *law to ensure that health coverage benefit designs do not have an*
14 *unreasonable discriminatory impact on chronically ill individuals,*
15 *and to ensure affordability of outpatient prescription drugs.*

16 (3) *Assignment of all or most prescription medications that treat*
17 *a specific medical condition to the highest cost tiers of a formulary*
18 *may effectively discourage enrollment by chronically ill individuals,*
19 *and may result in lower adherence to a prescription drug treatment*
20 *regimen.*

21 (b) *A nongrandfathered group health care service plan contract*
22 *that is offered, amended, or renewed on or after July 1, 2016, shall*

1 comply with this section. A nongrandfathered individual health
2 care service plan contract that is offered, amended, or renewed on
3 or after January 1, 2017, shall comply with this section. The
4 cost-sharing limits established by this section apply only to
5 outpatient prescription drugs covered by the contract that constitute
6 essential health benefits, as defined in Section 1367.005. This
7 section does not apply to Medi-Cal managed care contracts.

8 ~~(b) (1) A health care service plan that provides coverage for~~
9 ~~outpatient prescription drugs shall cover medically necessary~~
10 ~~prescription drugs.~~

11 ~~(2) A health care service plan that provides coverage for~~
12 ~~outpatient prescription drugs shall cover a medically necessary~~
13 ~~prescription drug for which there is not a therapeutic equivalent.~~

14 ~~(c) Copayments, coinsurance, and other cost sharing for~~
15 ~~outpatient prescription drugs shall be reasonable so as to allow~~
16 ~~access to medically necessary outpatient prescription drugs. In~~
17 ~~proposing cost sharing, the health care service plan shall consider~~
18 ~~the impact of cost sharing on medication adherence as~~
19 ~~demonstrated in peer-reviewed literature.~~

20 ~~(d)~~

21 ~~(c) Consistent with federal law and guidance, and~~
22 ~~notwithstanding Section 1342.7 and any regulations adopted~~
23 ~~pursuant to that section, a health care service plan that provides~~
24 ~~coverage for outpatient prescription drugs shall demonstrate that~~
25 ~~the formulary or formularies maintained by the health care service~~
26 ~~plan do not discourage the enrollment of individuals with health~~
27 ~~conditions and do not reduce the generosity of the benefit for~~
28 ~~enrollees with a particular condition.~~

29 ~~(1) A—For combination drug treatments that include~~
30 ~~antiretrovirals, a health care service plan contract shall cover a~~
31 ~~single-tablet drug regimen that is as effective as a multitablet~~
32 ~~regimen unless the health care service plan is able to demonstrate~~
33 ~~to the director, consistent with clinical guidelines and~~
34 ~~peer-reviewed scientific and medical literature, that the multitablet~~
35 ~~regimen is clinically equally or more effective and more likely to~~
36 ~~result in adherence to a drug regimen. A health care service plan~~
37 ~~contract shall cover an extended release prescription drug that is~~
38 ~~clinically equally or more effective than a nonextended release~~
39 ~~product unless the health care service plan is able to demonstrate~~
40 ~~to the director, consistent with clinical guidelines and~~

1 peer-reviewed scientific and medical literature, that the
2 nonextended release product is clinically equally or more effective
3 than the extended release product.

4 (2) A health care service plan contract shall not place most or
5 all of the prescription medications that treat a specific condition
6 on the highest cost tiers of a formulary unless the health care
7 service plan can demonstrate that such placement does not reduce
8 the generosity of the benefits for enrollees with a particular
9 condition. If there is more than one treatment that is the standard
10 of care for a specific condition, the health care service plan shall
11 not place most or all prescription medications that treat that
12 condition on the highest cost tiers. This shall not apply to any
13 medication for which there is a therapeutic equivalent available
14 on a lower cost tier.

15 (2) *No more than 50 percent of drugs approved by the United*
16 *States Food and Drug Administration (FDA) that are in the same*
17 *drug class may be assigned to the two highest cost tiers of a drug*
18 *formulary. All health care service plan formularies shall include*
19 *at least one drug in the lower cost tiers if all FDA-approved drugs*
20 *in the same drug class would otherwise qualify for the highest cost*
21 *tiers and at least three drugs in that class are available as*
22 *FDA-approved drugs . The drug or drugs assigned to the lower*
23 *cost tiers pursuant to this paragraph shall be the drug or drugs*
24 *that were most often prescribed during the immediately preceding*
25 *plan year, based on the health care service plan's experience.*

26 (3) For coverage offered in the individual market, the health
27 care service plan shall demonstrate that the formulary or
28 formularies maintained for coverage in the individual market are
29 the same or comparable to those maintained for coverage in the
30 group market.

31 (4) A health care service plan shall demonstrate to the director
32 that any limitation or utilization management is consistent with
33 and based on clinical guidelines and peer-reviewed scientific and
34 medical literature.

35 (e)

36 (d) (1) With respect to an individual or group health care service
37 plan contract subject to Section 1367.006, the copayment,
38 coinsurance, or any other form of cost sharing for a covered
39 outpatient prescription drug for an individual prescription *for a*
40 *supply of up to 30 days* shall not exceed ~~one-twenty-fourth~~ of the

1 ~~annual out-of-pocket limit applicable to individual coverage under~~
2 ~~Section 1367.006 for a supply of up to 30 days: two hundred fifty~~
3 ~~dollars (\$250), except as provided in paragraphs (2) and (3).~~

4 (2) *With respect to products with actuarial value at, or*
5 *equivalent to, the bronze level, cost sharing for a covered*
6 *outpatient prescription drug for an individual prescription for a*
7 *supply of up to 30 days shall not exceed five hundred dollars*
8 *(\$500).*

9 ~~(2)~~

10 (3) For a health care service plan contract that is a “high
11 deductible health plan” under the definition set forth in Section
12 223(c)(2) of Title 26 of the United States Code, paragraph (1) of
13 this subdivision shall apply only once an enrollee’s deductible has
14 been satisfied for the year.

15 ~~(f)~~

16 (e) (1) If a health care service plan contract maintains a drug
17 formulary grouped into tiers, including a fourth tier or specialty
18 tier, a health care service plan contract shall use the following
19 definitions for each tier of the drug formulary:

20 (A) Tier one shall consist of ~~preferred generic drugs and~~
21 ~~preferred brand name drugs if the cost to the health care service~~
22 ~~plan for a preferred brand name drug is comparable to those for~~
23 ~~generic drugs: most generic drugs and low cost preferred brand~~
24 ~~drugs.~~

25 (B) Tier two shall consist of nonpreferred generic drugs,
26 preferred brand name drugs, and any other drugs recommended
27 by the health care service plan’s pharmacy and therapeutics
28 committee based on safety and efficacy and not solely based on
29 the cost of the prescription ~~drug: drug, and which generally have~~
30 ~~a preferred and often less costly therapeutic alternative at a lower~~
31 ~~tier.~~

32 (C) Tier three shall consist of nonpreferred brand name drugs
33 that are recommended by the health care service plan’s pharmacy
34 and therapeutics committee based on safety and efficacy and not
35 solely based on the cost of the prescription drug.

36 (D) Tier four shall consist of ~~specialty~~ drugs that are biologics,
37 ~~which, according to the drugs that the federal Food and Drug~~
38 ~~Administration or the manufacturer, require distribution~~
39 ~~manufacturer requires to be distributed through a specialty~~
40 ~~pharmacy or the pharmacy, drugs that require the enrollee to have~~

1 ~~special training for self-administration or special monitoring.~~
 2 Specialty drugs may include prescription drugs that cost more than
 3 the Medicare Part D threshold if those drugs are recommended for
 4 Tier four by the health care service plan's pharmacy and
 5 therapeutics committee based on safety and efficacy, but placement
 6 shall not be solely based on the cost of the prescription drug. *or*
 7 *clinical monitoring for self-administration, or drugs that cost the*
 8 *health plan more than six hundred dollars (\$600) net of rebates.*

9 (2) This section does not require a health care service plan
 10 contract to include a fourth tier, but if a health care service plan
 11 contract includes a fourth tier, the health care service plan contract
 12 shall comply with this section. *tier.*

13 ~~(3) This section does not require the health care service plan's~~
 14 ~~pharmacy and therapeutics committee to consider the cost of the~~
 15 ~~prescription drug to the health care service plan.~~

16 ~~(g)~~

17 (f) A health care service plan contract shall ensure that the
 18 placement of prescription drugs on formulary tiers is ~~not based~~
 19 ~~solely on the cost of the prescription drug to the health care service~~
 20 ~~plan, but is based on clinically indicated, reasonable medical~~
 21 ~~management practices.~~

22 ~~(h)~~

23 (g) This section shall not be construed to require a health care
 24 service plan to impose cost sharing. This section shall not be
 25 construed to require cost sharing for prescription drugs that state
 26 or federal law otherwise requires to be provided without cost
 27 sharing.

28 ~~(i)~~

29 (h) This section does not require or authorize a health care
 30 service plan that contracts with the State Department of Health
 31 Care Services to provide services to Medi-Cal beneficiaries to
 32 provide coverage for prescription drugs that are not required
 33 pursuant to those programs or contracts, or to limit or exclude any
 34 prescription drugs that are required by those programs or contracts.

35 SEC. 2. Section 1367.24 of the Health and Safety Code is
 36 amended to read:

37 1367.24. (a) (1) Every health care service plan that provides
 38 prescription drug benefits shall maintain an expeditious process
 39 by which prescribing providers may obtain authorization for a
 40 medically necessary nonformulary prescription drug. On or before

1 July 1, 1999, every health care service plan that provides
2 prescription drug benefits shall file with the department a
3 description of its process for responding to authorization requests
4 for nonformulary drugs. Any changes to this process shall be filed
5 with the department pursuant to Section 1352. The plan shall
6 provide that the enrollee, the enrollee's designee, or the enrollee's
7 prescribing provider may seek an authorization for a nonformulary
8 prescription drug.

9 (2) Each plan shall respond to an authorization request within
10 72 hours following receipt of the authorization request for a
11 nonurgent authorization. If the plan grants the authorization request,
12 the plan shall provide coverage of the nonformulary drug for the
13 duration of the prescription, including refills.

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

22 ~~(4) If a plan imposes step therapy, the plan shall provide an~~
23 ~~expeditious process to authorize an exception to step therapy when~~
24 ~~medically necessary and to conform effectively and efficiently~~
25 ~~with continuity of care requirements of this chapter and federal~~
26 ~~law, and any regulations issued thereunder. The process to~~
27 ~~authorize an exception to step therapy shall be consistent with this~~
28 ~~section, including the timelines provided in this section.~~

29 ~~(5)~~

30 (4) Each plan shall provide a written description of its most
31 current process to its prescribing providers. For purposes of this
32 section, a prescribing provider shall include a provider authorized
33 to write a prescription, pursuant to subdivision (a) of Section 4040
34 of the Business and Professions Code, to treat a medical condition
35 of an enrollee.

36 (b) Any plan that disapproves a request made pursuant to
37 subdivision (a) by a prescribing provider to obtain authorization
38 for a nonformulary drug shall provide the reasons for the
39 disapproval in a notice provided to the enrollee. The notice shall
40 indicate that the enrollee may file a grievance with the plan if the

1 enrollee objects to the disapproval, including any alternative drug
2 or treatment offered by the plan. The notice shall comply with
3 subdivision (b) of Section 1368.02.

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

9 ~~(d) (1) A plan shall maintain a pharmacy and therapeutics~~
10 ~~committee that shall be responsible for developing, maintaining,~~
11 ~~and overseeing any drug formulary list. If the plan delegates~~
12 ~~responsibility for the formulary to any entity, the obligation of the~~
13 ~~plan to comply with this chapter shall not be waived.~~

14 ~~(2) The pharmacy and therapeutics committee board membership~~
15 ~~shall conform with both of the following:~~

16 ~~(A) Represent a sufficient number of clinical specialties to~~
17 ~~adequately meet the needs of enrollees.~~

18 ~~(B) Consist of a majority of individuals who are practicing~~
19 ~~physicians, practicing pharmacists, and other practicing health~~
20 ~~professionals who are licensed to prescribe drugs.~~

21 ~~(3) Members of the board shall abstain from voting on any issue~~
22 ~~in which the member has a conflict of interest with respect to the~~
23 ~~issuer or a pharmaceutical manufacturer.~~

24 ~~(4) At least 20 percent of the board membership shall not have~~
25 ~~a conflict of interest with respect to the issuer or any~~
26 ~~pharmaceutical manufacturer.~~

27 ~~(5) The pharmacy and therapeutics committee shall meet at least~~
28 ~~quarterly and shall maintain written documentation of the rationale~~
29 ~~for its decisions regarding the development of, or revisions to, the~~
30 ~~formulary drug list.~~

31 ~~(6) The pharmacy and therapeutics committee shall do all of~~
32 ~~the following:~~

33 ~~(A) Develop and document procedures to ensure appropriate~~
34 ~~drug review and inclusion.~~

35 ~~(B) Base clinical decisions on the strength of the scientific~~
36 ~~evidence and standards of practice, including assessing~~
37 ~~peer-reviewed medical literature, pharmacoeconomic studies,~~
38 ~~outcomes research data, and other related information.~~

39 ~~(C) Consider the therapeutic advantages of drugs in terms of~~
40 ~~safety and efficacy when selecting formulary drugs.~~

1 ~~(D) Review policies that guide exceptions and other utilization~~
2 ~~management processes, including drug utilization review, quantity~~
3 ~~limits, and therapeutic interchange.~~

4 ~~(E) Evaluate and analyze treatment protocols and procedures~~
5 ~~related to the plan's formulary at least annually.~~

6 ~~(F) Review and approve all clinical prior authorization criteria,~~
7 ~~step therapy protocols, and quantity limit restrictions applied to~~
8 ~~each covered drug.~~

9 ~~(G) Review new federal Food and Drug~~
10 ~~Administration-approved drugs and new uses for existing drugs.~~

11 ~~(H) Ensure the plan's formulary drug list or lists cover a range~~
12 ~~of drugs across a broad distribution of therapeutic categories and~~
13 ~~classes and recommended drug treatment regimens that treat all~~
14 ~~disease states and does not discourage enrollment by any group~~
15 ~~of enrollees.~~

16 ~~(I) Ensure the plan's formulary drug list or lists provide~~
17 ~~appropriate access to drugs that are included in broadly accepted~~
18 ~~treatment guidelines and that are indicative of general best practices~~
19 ~~at the time.~~

20 ~~(e) (1) A health care service plan may impose prior~~
21 ~~authorization requirements on prescription drug benefits, consistent~~
22 ~~with the requirements of this chapter.~~

23 ~~(2) (A) When there is more than one drug that is appropriate~~
24 ~~for the treatment of a medical condition, a plan may require step~~
25 ~~therapy. A plan that requires step therapy shall comply with the~~
26 ~~requirements specified in paragraph (4) of subdivision (a).~~

27 ~~(B) In circumstances where an enrollee is changing plans, the~~
28 ~~new plan shall not require the enrollee to repeat step therapy when~~
29 ~~that enrollee is already being treated for a medical condition by a~~
30 ~~prescription drug provided that the drug is appropriately prescribed~~
31 ~~and is considered safe and effective for the enrollee's condition.~~
32 ~~Nothing in this section shall preclude the new plan from imposing~~
33 ~~a prior authorization requirement pursuant to this section for the~~
34 ~~continued coverage of a prescription drug prescribed pursuant to~~
35 ~~step therapy imposed by the former plan, or preclude the~~
36 ~~prescribing provider from prescribing another drug covered by the~~
37 ~~new plan that is medically appropriate for the enrollee.~~

38 ~~(3) A plan shall provide coverage for the medically necessary~~
39 ~~dosage and quantity of the drug prescribed for the treatment of a~~

1 ~~medical condition consistent with professionally recognized~~
2 ~~standards of practice.~~

3 ~~(4) A plan that provides essential health benefits shall allow an~~
4 ~~enrollee to access prescription drug benefits at an in-network retail~~
5 ~~pharmacy unless the prescription drug is subject to restricted~~
6 ~~distribution by the federal Food and Drug Administration or~~
7 ~~requires special handling, provider coordination, or patient~~
8 ~~education that cannot be provided by a retail pharmacy. A health~~
9 ~~care service plan that provides essential health benefits may charge~~
10 ~~an enrollee a different cost sharing for obtaining a covered drug~~
11 ~~at a retail pharmacy, but all cost sharing shall count toward the~~
12 ~~plan's annual limitation on cost sharing consistent with Section~~
13 ~~1367.006.~~

14 ~~(f)~~
15 ~~(d) The process described in subdivision (a) by which enrollees~~
16 ~~may obtain medically necessary nonformulary drugs, including~~
17 ~~specified timelines for responding to prescribing provider~~
18 ~~authorization requests, shall be described in evidence of coverage~~
19 ~~and disclosure forms, as required by subdivision (a) of Section~~
20 ~~1363, issued on or after July 1, 1999.~~

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

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

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

38 ~~(3) Any plan arrangements with prescribing providers, medical~~
39 ~~groups, individual practice associations, pharmacists, contracting~~
40 ~~pharmaceutical benefit management companies, or other entities~~

1 that are associated with activities of the plan to encourage
2 formulary compliance or otherwise manage prescription drug
3 benefits.

4 ~~(h)~~

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

12 ~~(i)~~

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

16 ~~(j)~~

17 (h) For purposes of this section, ~~the following definitions shall~~
18 ~~apply:~~

19 ~~(1) “Authorization” “authorization” means approval by the~~
20 ~~health care service plan to provide payment for the prescription~~
21 ~~drug.~~

22 ~~(2) “Step therapy” means a type of protocol that specifies the~~
23 ~~sequence in which different prescription drugs for a given medical~~
24 ~~condition and medically appropriate for a particular patient are to~~
25 ~~be prescribed.~~

26 ~~(k)~~

27 (i) (1) Nonformulary prescription drugs shall include any drug
28 for which an enrollee’s copayment or out-of-pocket costs are
29 different than the copayment for a formulary prescription drug,
30 except as otherwise provided by law or regulation or in cases in
31 which the drug has been excluded in the plan contract pursuant to
32 Section 1342.7.

33 (2) If a nonformulary drug is authorized consistent with this
34 section, the cost sharing shall be the same as for a formulary drug
35 consistent with subdivision (e) of Section 1342.71.

36 (j) *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 this
2 chapter.

3 (†)

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

11 SEC. 3. Section 1367.41 is added to the Health and Safety
12 Code, immediately following Section 1367.4, to read:

13 1367.41. (a) A plan shall maintain a pharmacy and
14 therapeutics committee that shall be responsible for developing,
15 maintaining, and overseeing any drug formulary list. If the plan
16 delegates responsibility for the formulary to any entity, the
17 obligation of the plan to comply with this chapter shall not be
18 waived.

19 (b) The pharmacy and therapeutics committee board
20 membership shall conform with both of the following:

21 (1) Represent a sufficient number of clinical specialties to
22 adequately meet the needs of enrollees.

23 (2) Consist of a majority of individuals who are practicing
24 physicians, practicing pharmacists, and other practicing health
25 professionals who are licensed to prescribe drugs.

26 (c) Members of the board shall abstain from voting on any issue
27 in which the member has a conflict of interest with respect to the
28 issuer or a pharmaceutical manufacturer.

29 (d) At least 20 percent of the board membership shall not have
30 a conflict of interest with respect to the issuer or any
31 pharmaceutical manufacturer.

32 (e) The pharmacy and therapeutics committee shall meet at
33 least quarterly and shall maintain written documentation of the
34 rationale for its decisions regarding the development of, or
35 revisions to, the formulary drug list.

36 (f) The pharmacy and therapeutics committee shall do all of the
37 following:

38 (1) Develop and document procedures to ensure appropriate
39 drug review and inclusion.

1 (2) Base clinical decisions on the strength of the scientific
2 evidence and standards of practice, including assessing
3 peer-reviewed medical literature, pharmacoeconomic studies,
4 outcomes research data, and other related information.

5 (3) Consider the therapeutic advantages of drugs in terms of
6 safety and efficacy when selecting formulary drugs.

7 (4) Review policies that guide exceptions and other utilization
8 management processes, including drug utilization review, quantity
9 limits, and therapeutic interchange.

10 (5) Evaluate and analyze treatment protocols and procedures
11 related to the plan's formulary at least annually.

12 (6) Review and approve all clinical prior authorization criteria,
13 step therapy protocols, and quantity limit restrictions applied to
14 each covered drug.

15 (7) Review new federal Food and Drug Administration-approved
16 drugs and new uses for existing drugs.

17 (8) Ensure that the plan's formulary drug list or lists cover a
18 range of drugs across a broad distribution of therapeutic
19 categories and classes and recommended drug treatment regimens
20 that treat all disease states and do not discourage enrollment by
21 any group of enrollees.

22 (9) Ensure that the plan's formulary drug list or lists provide
23 appropriate access to drugs that are included in broadly accepted
24 treatment guidelines and that are indicative of general best
25 practices at the time.

26 SEC. 4. Section 1367.42 is added to the Health and Safety
27 Code, to read:

28 1367.42. (a) A plan that provides essential health benefits
29 shall allow an enrollee to access prescription drug benefits at an
30 in-network retail pharmacy unless the prescription drug is subject
31 to restricted distribution by the federal Food and Drug
32 Administration or requires special handling, provider coordination,
33 or patient education that cannot be provided by a retail pharmacy.

34 (b) A nongrandfathered individual or small group health plan
35 contract may charge an enrollee a different cost sharing for
36 obtaining a covered drug at a retail pharmacy, but all cost sharing
37 shall count toward the plan's annual limitation on cost sharing
38 consistent with Section 1367.006.

1 ~~SEC. 3.~~

2 *SEC. 5.* Section 1367.205 of the Health and Safety Code is
 3 amended to read:

4 1367.205. (a) In addition to the list required to be provided
 5 under Section 1367.20, a health care service plan that provides
 6 prescription drug benefits and maintains one or more drug
 7 formularies shall do all of the following:

8 (1) Post the formulary or formularies for each product offered
 9 by the plan on the plan’s Internet Web site in a manner that is
 10 accessible and searchable by potential enrollees, enrollees,
 11 providers, the general public, the department, and federal agencies
 12 as required by federal law or regulations.

13 (2) Update the formularies posted pursuant to paragraph (1)
 14 with any change to those formularies on a monthly basis.

15 (3) No later than six months after the date that a standard
 16 formulary template is developed under subdivision (b), use that
 17 template to display the formulary or formularies for each product
 18 offered by the plan.

19 (b) (1) By January 1, 2017, the department and the Department
 20 of Insurance shall jointly, and with input from interested parties
 21 from at least one public meeting, develop a standard formulary
 22 template for purposes of paragraph (3) of subdivision (a). In
 23 developing the template, the department and Department of
 24 Insurance shall take into consideration existing requirements for
 25 reporting of formulary information established by the federal
 26 Centers for Medicare and Medicaid Services. To the extent feasible,
 27 in developing the template, the department and the Department of
 28 Insurance shall evaluate a way to include on the template, in
 29 addition to the information required to be included under paragraph
 30 (2), cost-sharing information for drugs subject to coinsurance.

31 (2) The standard formulary template shall include the
 32 notification described in subdivision (c) of Section 1363.01, and
 33 as applied to a particular formulary for a product offered by a plan,
 34 shall do all of the following:

35 (A) Include information on cost sharing tiers and utilization
 36 controls, including prior authorization or step therapy requirements,
 37 for each drug covered by the product.

38 (B) Indicate any drugs on the formulary that are preferred over
 39 other drugs on the formulary.

1 (C) Include information to educate enrollees about the
2 differences between drugs administered or provided under a health
3 care service plan’s medical benefit and drugs prescribed under a
4 health care service plan’s prescription drug benefit and about how
5 to obtain coverage information regarding drugs that are not covered
6 under the plan’s prescription drug benefit.

7 (D) Include information to educate enrollees that health care
8 service plans that provide prescription drug benefits are required
9 to have a method for enrollees to obtain prescription drugs not
10 listed in the health plan drug formulary if the drugs are deemed
11 medically necessary by a clinician pursuant to Section 1367.24.

12 (E) Include information on which medications are covered,
13 including both generic and brand name.

14 (F) Include information on what tier of the plan’s drug formulary
15 each medication is in.

16 (c) For purposes of this section, “formulary” means the complete
17 list of drugs preferred for use and eligible for coverage under a
18 health care service plan product and includes the drugs covered
19 under the pharmacy benefit of the product.

20 ~~SEC. 4.~~

21 *SEC. 6.* Section 10123.192 of the Insurance Code is amended
22 to read:

23 10123.192. (a) A health insurer that provides prescription drug
24 benefits and maintains one or more drug formularies shall do all
25 of the following:

26 (1) Post the formulary or formularies for each product offered
27 by the insurer on the insurer’s Internet Web site in a manner that
28 is accessible and searchable by potential insureds, insureds,
29 providers, the general public, the department, and federal agencies
30 as required by federal law or regulations.

31 (2) Update the formularies posted pursuant to paragraph (1)
32 with any change to those formularies on a monthly basis.

33 (3) No later than six months after the date that a standard
34 formulary template is developed under subdivision (b), use that
35 template to display the formulary or formularies for each product
36 offered by the insurer.

37 (b) (1) By January 1, 2017, the department and the Department
38 of Managed Health Care shall jointly, and with input from
39 interested parties from at least one public meeting, develop a
40 standard formulary template for purposes of paragraph (3) of

1 subdivision (a). In developing the template, the department and
2 Department of Managed Health Care shall take into consideration
3 existing requirements for reporting of formulary information
4 established by the federal Centers for Medicare and Medicaid
5 Services. To the extent feasible, in developing the template, the
6 department and the Department of Managed Health Care shall
7 evaluate a way to include on the template, in addition to the
8 information required to be included under paragraph (2),
9 cost-sharing information for drugs subject to coinsurance.

10 (2) The standard formulary template shall include a notification
11 that the presence of a drug on the insurer's formulary does not
12 guarantee that an insured will be prescribed that drug by his or her
13 prescribing provider for a particular medical condition. As applied
14 to a particular formulary for a product offered by an insurer, the
15 standard formulary template shall do all of the following:

16 (A) Include information on cost sharing tiers and utilization
17 controls, including prior authorization or step therapy requirements,
18 for each drug covered by the product.

19 (B) Indicate any drugs on the formulary that are preferred over
20 other drugs on the formulary.

21 (C) Include information to educate insureds about the differences
22 between drugs administered or provided under a health insurer's
23 medical benefit and drugs prescribed under a health insurer's
24 prescription drug benefit and about how to obtain coverage
25 information about drugs that are not covered under the health
26 insurer's prescription drug benefit.

27 (D) Include information to educate insureds that health insurers
28 that provide prescription drug benefits are required to have a
29 method for insureds to obtain prescription drugs not listed in the
30 health insurer's drug formulary if the drugs are deemed to be
31 medically necessary by a clinician pursuant to Section 1367.24 of
32 the Health and Safety Code, as required by clause (iv) of
33 subparagraph (A) of paragraph (2) of subdivision (a) of Section
34 10112.27.

35 (E) Include information on which medications are covered,
36 including both generic and brand name.

37 (F) Include information on what tier of the health insurer's drug
38 formulary each medication is in.

39 (c) The commissioner may adopt regulations as may be
40 necessary to carry out the purposes of this section. In adopting

1 regulations, the commissioner shall comply with Chapter 3.5
2 (commencing with Section 11340) of Part 1 of Division 3 of Title
3 2 of the Government Code.

4 (d) For purposes of this section, “formulary” means the complete
5 list of drugs preferred for use and eligible for coverage under a
6 health insurance product and includes the drugs covered under the
7 pharmacy benefit of the product.

8 ~~SEC. 5.~~

9 *SEC. 7.* Section 10123.193 is added to the Insurance Code, to
10 read:

11 10123.193. (a) *The Legislature hereby finds and declares all*
12 *of the following:*

13 (1) *The federal Patient Protection and Affordable Care Act, its*
14 *implementing regulations and guidance, and related state law*
15 *prohibit discrimination based on a person’s expected length of*
16 *life, present or predicted disability, degree of medical dependency,*
17 *quality of life, or other health conditions, including benefit designs*
18 *that have the effect of discouraging the enrollment of individuals*
19 *with significant health needs.*

20 (2) *The Legislature intends to build on existing state and federal*
21 *law to ensure that health coverage benefit designs do not have an*
22 *unreasonable discriminatory impact on chronically ill individuals,*
23 *and to ensure affordability of outpatient prescription drugs.*

24 (3) *Assignment of all or most prescription medications that treat*
25 *a specific medical condition to the highest cost tiers of a formulary*
26 *may effectively discourage enrollment by chronically ill individuals,*
27 *and may result in lower adherence to a prescription drug treatment*
28 *regimen.*

29 (b) A nongrandfathered group policy of health insurance that
30 is offered, amended, or renewed on or after July 1, 2016, shall
31 comply with this section. A nongrandfathered individual policy
32 of health insurance that is offered, amended, or renewed on or after
33 January 1, 2017, shall comply with this section. The cost-sharing
34 limits established by this section apply only to outpatient
35 prescription drugs covered by the policy that constitute essential
36 health benefits, as defined by Section 10112.27.

37 ~~(b)~~

38 (c) (1) A policy of health insurance that provides coverage for
39 outpatient prescription drugs shall cover medically necessary
40 prescription drugs.

1 (2) A policy of health insurance that provides coverage for
2 outpatient prescription drugs shall cover a medically necessary
3 prescription drug for which there is not a therapeutic equivalent.

4 (e)

5 (d) Copayments, coinsurance, and other cost sharing for
6 outpatient prescription drugs shall be reasonable so as to allow
7 access to medically necessary outpatient prescription drugs. ~~In~~
8 ~~proposing cost sharing, the health insurer shall consider the impact~~
9 ~~of cost sharing on medication adherence as demonstrated in~~
10 ~~peer-reviewed literature.~~

11 (d)

12 (e) Consistent with federal law and guidance, a policy of health
13 insurance that provides coverage for outpatient prescription drugs
14 shall demonstrate that the formulary or formularies maintained by
15 the health insurer do not discourage the enrollment of individuals
16 with health conditions and do not reduce the generosity of the
17 benefit for insureds with a particular condition.

18 (1) ~~A—For combination drug treatments that include~~
19 ~~antiretrovirals, a policy of health insurance shall cover a~~
20 ~~single-tablet drug regimen that is as effective as a multitablet~~
21 ~~regimen unless the health insurer is able to demonstrate to the~~
22 ~~commissioner, consistent with clinical guidelines and~~
23 ~~peer-reviewed scientific and medical literature, that the multitablet~~
24 ~~regimen is clinically equally or more effective and more likely to~~
25 ~~result in adherence to a drug regimen. A policy of health insurance~~
26 ~~shall cover an extended release prescription drug that is clinically~~
27 ~~equally or more effective than a nonextended release product unless~~
28 ~~the health insurer is able to demonstrate to the commissioner,~~
29 ~~consistent with clinical guidelines and peer-reviewed scientific~~
30 ~~and medical literature, that the nonextended release product is~~
31 ~~clinically equally or more effective than the extended release~~
32 ~~product.~~

33 (2) ~~A policy of health insurance shall not place most or all of~~
34 ~~the prescription medications that treat a specific condition on the~~
35 ~~highest cost tiers of a formulary unless the health insurer can~~
36 ~~demonstrate that such placement does not reduce the generosity~~
37 ~~of the benefits for insureds with a particular condition. If there is~~
38 ~~more than one treatment that is the standard of care for a specific~~
39 ~~condition, the health insurer shall not place most or all prescription~~
40 ~~medications that treat that condition on the highest cost tiers. This~~

1 shall not apply to any medication for which there is a therapeutic
2 equivalent available on a lower cost tier.

3 (2) *No more than 50 percent of drugs approved by the United*
4 *States Food and Drug Administration (FDA) that are in the same*
5 *drug class may be assigned to the two highest cost tiers of a drug*
6 *formulary. All health insurer formularies shall include at least*
7 *one drug in the lower cost tiers if all FDA-approved drugs in the*
8 *same drug class would otherwise qualify for the highest cost tiers*
9 *and at least three drugs in that class are available as*
10 *FDA-approved drugs. The drug or drugs assigned to the lower*
11 *cost tiers pursuant to this paragraph shall be the drug or drugs*
12 *that were most often prescribed during the immediately preceding*
13 *plan year, based on the health insurer's experience.*

14 (3) For coverage offered in the individual market, the health
15 insurer shall demonstrate that the formulary or formularies
16 maintained for coverage in the individual market are the same or
17 comparable to those maintained for coverage in the group market.

18 (4) A health insurer shall demonstrate to the commissioner that
19 any limitation or utilization management is consistent with and
20 based on clinical guidelines and peer-reviewed scientific and
21 medical literature.

22 (e)

23 (f) (1) With respect to an individual or group policy of health
24 insurance subject to Section 10112.28, the copayment, coinsurance,
25 or any other form of cost sharing for a covered outpatient
26 prescription drug for an individual prescription *for a supply of up*
27 *to 30 days shall not exceed ~~one twenty-fourth of the annual~~*
28 *out-of-pocket limit applicable to individual coverage under Section*
29 *10112.28 for a supply of up to 30 days: two hundred fifty dollars*
30 *(\$250), except as provided in paragraphs (2) and (3).*

31 (2) *With respect to products with actuarial value at or equivalent*
32 *to the bronze level, cost sharing for a covered outpatient*
33 *prescription drug for an individual prescription for a supply of up*
34 *to 30 days shall not exceed five hundred dollars (\$500).*

35 (2)

36 (3) For a policy of health insurance that is a “high deductible
37 health plan” under the definition set forth in Section 223(c)(2) of
38 Title 26 of the United States Code, paragraph (1) of this subdivision
39 shall apply only once an insured's deductible has been satisfied
40 for the year.

1 (f)

2 (g) (1) If a policy of health insurance maintains a drug
3 formulary grouped into tiers, including a fourth tier or specialty
4 tier, a policy of health insurance shall use the following definitions
5 for each tier of the drug formulary:

6 (A) Tier one shall consist of ~~preferred generic drugs and~~
7 ~~preferred brand name drugs if the cost to the health insurer for a~~
8 ~~preferred brand name drug is comparable to those for generic~~
9 ~~drugs.~~ *most generic drugs and low-cost preferred brand drugs.*

10 (B) Tier two shall consist of nonpreferred generic drugs,
11 preferred brand name drugs, and any other drugs recommended
12 by the health insurer's pharmacy and therapeutics committee based
13 on safety and efficacy and not solely based on the cost of the
14 prescription drug.

15 (C) Tier three shall consist of nonpreferred brand name drugs
16 that are recommended by the health insurer's pharmacy and
17 therapeutics committee based on safety and efficacy and not solely
18 based on the cost of the prescription ~~drug.~~ *drug, and which*
19 *generally have a preferred and often less costly therapeutic*
20 *alternative at a lower tier.*

21 (D) Tier four shall consist of ~~specialty~~ drugs that are biologics,
22 ~~which, according to the drugs that the federal Food and Drug~~
23 ~~Administration or the manufacturer, require distribution~~
24 ~~manufacturer requires to be distributed~~ through a specialty
25 ~~pharmacy or the pharmacy,~~ *drugs that require the insured to have*
26 *special training for self-administration or special monitoring.*
27 *Specialty drugs may include prescription drugs that cost more than*
28 *the Medicare Part D threshold if those drugs are recommended for*
29 *Tier four by the health insurer's pharmacy and therapeutics*
30 *committee based on safety and efficacy, but placement shall not*
31 *be solely based on the cost of the prescription drug.* *or clinical*
32 *monitoring for self-administration, or drugs that cost the health*
33 *insurer more than six hundred dollars (\$600) net of rebates.*

34 (2) This section does not require a policy of health insurance to
35 include a fourth tier, ~~but if a policy of health insurance includes a~~
36 ~~fourth tier, the policy of health insurance shall comply with this~~
37 ~~section.~~ *tier.*

38 (3) ~~This section does not require the health insurer's pharmacy~~
39 ~~and therapeutics committee to consider the cost of the prescription~~
40 ~~drug to the health insurer.~~

1 ~~(g)~~

2 (h) This section shall not be construed to require a health insurer
3 to impose cost sharing. This section shall not be construed to
4 require cost sharing for prescription drugs that state or federal law
5 otherwise requires to be provided without cost sharing.

6 ~~(h)~~

7 (i) A policy of health insurance shall ensure that the placement
8 of prescription drugs on formulary tiers ~~is not based solely on the~~
9 ~~cost of the prescription drug to the health insurer, but is based on~~
10 clinically indicated, reasonable medical management practices.

11 ~~SEC. 6.~~

12 *SEC. 8.* Section 10123.201 is added to the Insurance Code, to
13 read:

14 10123.201. (a) (1) Every health insurer that provides
15 prescription drug benefits shall maintain an expeditious process
16 by which prescribing providers may obtain authorization for a
17 medically necessary nonformulary prescription drug. On or before
18 July 1, 2016, every insurer that provides prescription drug benefits
19 shall file with the commissioner a description of its process for
20 responding to authorization requests for nonformulary drugs. Any
21 changes to this process shall be filed with the commissioner. The
22 insurer shall provide that the insured, the insured's designee, or
23 the insured's prescribing provider may seek an authorization for
24 a nonformulary prescription drug.

25 (2) Each insurer shall respond to an authorization request within
26 72 hours following receipt of the authorization request for a
27 nonurgent authorization. If the insurer grants the authorization
28 request, the insurer shall provide coverage of the nonformulary
29 drug for the duration of the prescription, including refills.

30 (3) Each insurer shall provide that an urgent authorization may
31 be obtained within 24 hours if an insured is suffering from a health
32 condition that may seriously jeopardize the insured's life, health,
33 or ability to regain maximum function, or if an insured is
34 undergoing a current course of treatment using a nonformulary
35 prescription drug. An insurer that grants an exception based on
36 these urgent circumstances shall provide coverage of the
37 nonformulary prescription drug for the duration of that urgent
38 condition.

39 (4) If an insurer imposes step therapy, the insurer shall provide
40 an expeditious process to authorize an exception to step therapy

1 when medically necessary and to conform effectively and
2 efficiently with continuity of care requirements of this part and
3 federal law, and any regulations issued thereunder. The process
4 to authorize an exception to step therapy shall be consistent with
5 this section, including the timelines provided in this section.

6 (5) Each insurer shall provide a written description of its most
7 current process to its prescribing providers. For purposes of this
8 section, a prescribing provider shall include a provider authorized
9 to write a prescription, pursuant to subdivision (a) of Section 4040
10 of the Business and Professions Code, to treat a medical condition
11 of an insured.

12 (b) Any insurer that disapproves a request made pursuant to
13 subdivision (a) by a prescribing provider to obtain authorization
14 for a nonformulary drug shall provide the reasons for the
15 disapproval in a notice provided to the insured. The notice shall
16 indicate that the insured may file a grievance with the insurer if
17 the insured objects to the disapproval, including any alternative
18 drug or treatment offered by the insurer. The notice shall comply
19 with Section 10133.661.

20 (c) (1) An insurer shall maintain a pharmacy and therapeutics
21 committee that shall be responsible for developing, maintaining,
22 and overseeing any drug formulary list. If the insurer delegates
23 responsibility for the formulary to any entity, the obligation of the
24 insurer to comply with this part shall not be waived.

25 (2) The pharmacy and therapeutics committee board membership
26 shall conform with both of the following:

27 (A) Represent a sufficient number of clinical specialties to
28 adequately meet the needs of insureds.

29 (B) Consist of a majority of individuals who are practicing
30 physicians, practicing pharmacists, and other practicing health
31 professionals who are licensed to prescribe drugs.

32 (3) Members of the board shall abstain from voting on any issue
33 in which the member has a conflict of interest with respect to the
34 issuer or a pharmaceutical manufacturer.

35 (4) At least 20 percent of the board membership shall not have
36 a conflict of interest with respect to the issuer or any
37 pharmaceutical manufacturer.

38 (5) The pharmacy and therapeutics committee shall meet at least
39 quarterly and shall maintain written documentation of the rationale

1 for its decisions regarding the development of, or revisions to, the
2 formulary drug list.

3 (6) The pharmacy and therapeutics committee shall do all of
4 the following:

5 (A) Develop and document procedures to ensure appropriate
6 drug review and inclusion.

7 (B) Base clinical decisions on the strength of the scientific
8 evidence and standards of practice, including assessing
9 peer-reviewed medical literature, pharmacoeconomic studies,
10 outcomes research data, and other related information.

11 (C) Consider the therapeutic advantages of drugs in terms of
12 safety and efficacy when selecting formulary drugs.

13 (D) Review policies that guide exceptions and other utilization
14 management processes, including drug utilization review, quantity
15 limits, and therapeutic interchange.

16 (E) Evaluate and analyze treatment protocols and procedures
17 related to the insurer's formulary at least annually.

18 (F) Review and approve all clinical prior authorization criteria,
19 step therapy protocols, and quantity limit restrictions applied to
20 each covered drug.

21 (G) Review new federal Food and Drug
22 Administration-approved drugs and new uses for existing drugs.

23 (H) Ensure the insurer's formulary drug list or lists cover a range
24 of drugs across a broad distribution of therapeutic categories and
25 classes and recommended drug treatment regimens that treat all
26 disease states and does not discourage enrollment by any group
27 of insureds.

28 (I) Ensure the insurer's formulary drug list or lists provide
29 appropriate access to drugs that are included in broadly accepted
30 treatment guidelines and that are indicative of general best practices
31 at the time.

32 (d) (1) A health insurer may impose prior authorization
33 requirements on prescription drug benefits, consistent with the
34 requirements of this part.

35 (2) (A) When there is more than one drug that is appropriate
36 for the treatment of a medical condition, a health insurer may
37 require step therapy. A health insurer that requires step therapy
38 shall comply with the requirements specified in paragraph (4) of
39 subdivision (a).

1 (B) In circumstances where an insured is changing policies, the
2 new policy shall not require the insureds to repeat step therapy
3 when that insured is already being treated for a medical condition
4 by a prescription drug provided that the drug is appropriately
5 prescribed and is considered safe and effective for the insured's
6 condition. Nothing in this section shall preclude the new policy
7 from imposing a prior authorization requirement pursuant to
8 subdivision (a) for the continued coverage of a prescription drug
9 prescribed pursuant to step therapy imposed by the former policy,
10 or preclude the prescribing provider from prescribing another drug
11 covered by the new policy that is medically appropriate for the
12 insured.

13 (3) An insurer shall provide coverage for the medically
14 necessary dosage and quantity of the drug prescribed for the
15 treatment of a medical condition consistent with professionally
16 recognized standards of practice.

17 (4) An insurer that provides essential health benefits shall allow
18 an insured to access prescription drug benefits at an in-network
19 retail pharmacy unless the prescription drug is subject to restricted
20 distribution by the federal Food and Drug Administration or
21 requires special handling, provider coordination, or patient
22 education that cannot be provided by a retail pharmacy. An insurer
23 that provides essential health benefits may charge an insured a
24 different cost sharing for obtaining a covered drug at a retail
25 pharmacy, but all cost sharing shall count toward the policy's
26 annual limitation on cost sharing consistent with Section 10112.28.

27 (e) The process described in subdivision (a) by which insureds
28 may obtain medically necessary nonformulary drugs, including
29 specified timelines for responding to prescribing provider
30 authorization requests, shall be described in evidence of coverage
31 and disclosure forms, as required by Section 10603, issued on or
32 after January 1, 2016.

33 (f) Every health insurer that provides prescription drug benefits
34 shall maintain all of the following information, which shall be
35 made available to the commissioner upon request:

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

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

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

14 (g) If an insurer provides prescription drug benefits, the
15 commissioner shall, as part of its market conduct examination,
16 review the performance of the insurer in providing those benefits,
17 including, but not limited to, a review of the procedures and
18 information maintained pursuant to this section, and describe the
19 performance of the insurer as part of its report issued as part of its
20 market conduct examination.

21 (h) The commissioner shall not publicly disclose any information
22 reviewed pursuant to this section that is determined by the
23 commissioner to be confidential pursuant to state law.

24 (i) For purposes of this section, the following definitions shall
25 apply:

26 (1) "Authorization" means approval by the health insurer to
27 provide payment for the prescription drug.

28 (2) "Step therapy" means a type of protocol that specifies the
29 sequence in which different prescription drugs for a given medical
30 condition and medically appropriate for a particular patient are to
31 be prescribed.

32 (j) (1) Nonformulary prescription drugs shall include any drug
33 for which an insured's copayment or out-of-pocket costs are
34 different than the copayment for a formulary prescription drug,
35 except as otherwise provided by law or regulation.

36 (2) If a nonformulary drug is authorized consistent with this
37 section, the cost sharing shall be the same as for a formulary drug
38 consistent with subdivision (e) of Section 10123.193.

39 (k) *Nothing in this section shall be construed to affect an*
40 *insured's or policyholder's eligibility to submit a complaint to the*

1 *department for review or to apply to the department for an*
2 *independent medical review.*

3 ~~(k)~~

4 *(l) Nothing in this section shall be construed to restrict or impair*
5 *the application of any other provision of this part.*

6 ~~SEC. 7.~~

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