

AMENDED IN SENATE SEPTEMBER 1, 2015

AMENDED IN SENATE JULY 16, 2015

AMENDED IN SENATE JULY 7, 2015

AMENDED IN SENATE JUNE 24, 2015

AMENDED IN ASSEMBLY JUNE 1, 2015

AMENDED IN ASSEMBLY MAY 20, 2015

AMENDED IN ASSEMBLY MAY 4, 2015

AMENDED IN ASSEMBLY APRIL 7, 2015

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

LEGISLATIVE COUNSEL'S DIGEST

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

(1) 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 prohibit the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment of individuals with health conditions and from reducing the generosity of the benefit for enrollees or insureds with a particular condition. The bill, until January 1, ~~2021~~, 2020, would provide that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as ~~specified~~. *specified, and would prohibit, for a nongrandfathered individual or small group plan contract or policy, the deductible for outpatient drugs from exceeding a specified amount.* 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 prescription drug regimen for combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, as specified. ~~The bill would prohibit, except as specified, a plan contract or policy from placing 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 bill, until January 1, 2020, 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 care service plan contract or health insurer insurance policy* 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, *nonformulary drugs determined to be medically necessary*, and, for an insurer, would require copayments, coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable.

This bill would make these provisions applicable to nongrandfathered ~~group health care service plan contracts or health insurance policies~~

~~that are offered, renewed, or amended on or after July 1, 2016, and applicable to nongrandfathered individual health care service plan contracts or health insurance policies that are offered, renewed, or amended on or after January 1, 2017.~~

(2) 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 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 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 insured changing policies, would prohibit a new insurer from requiring the insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. ~~The~~ *For plan years commencing on or after January 1, 2017, 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, commencing January 1, 2017, 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.

(3) 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.

(4) 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 life,  
8 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  
19 individuals, and may result in lower adherence to a prescription  
20 drug treatment regimen.

1 (b) ~~A nongrandfathered group health care service plan contract~~  
2 ~~that is offered, amended, or renewed on or after July 1, 2016, shall~~  
3 ~~comply with this section. A nongrandfathered individual health~~  
4 ~~care service plan contract that is offered, amended, or renewed on~~  
5 ~~or after January 1, 2017, shall comply with this section. The~~  
6 ~~cost-sharing limits established by this section apply only to~~  
7 ~~outpatient prescription drugs covered by the contract that constitute~~  
8 ~~essential health benefits, as defined in Section 1367.005. This~~  
9 ~~section does not apply to Medi-Cal managed care contracts.~~

10 (c) (1) *A health care service plan contract that provides*  
11 *coverage for outpatient prescription drugs shall cover medically*  
12 *necessary prescription drugs, including nonformulary drugs*  
13 *determined to be medically necessary consistent with this chapter.*

14 (2) *If a nonformulary drug is authorized consistent with this*  
15 *chapter, the cost sharing shall be the same as for a formulary drug.*

16 ~~(e) Consistent~~

17 (d) (1) ~~Consistent with federal law and guidance, and~~  
18 ~~notwithstanding Section 1342.7 and any regulations adopted~~  
19 ~~pursuant to that section, guidance, the formulary or formularies~~  
20 ~~for outpatient prescription drugs maintained by the health care~~  
21 ~~service plan shall not discourage the enrollment of individuals~~  
22 ~~with health conditions and shall not reduce the generosity of the~~  
23 ~~benefit for enrollees with a particular condition. condition in a~~  
24 ~~manner that is not based on a clinical indication or reasonable~~  
25 ~~medical management practices. Section 1342.7 and any regulations~~  
26 ~~adopted pursuant to that section shall be interpreted in a manner~~  
27 ~~that is consistent with this section.~~

28 ~~(1)~~

29 (2) For combination antiretroviral drug treatments that are  
30 medically necessary for the treatment of AIDS/HIV, a health care  
31 service plan contract shall cover a single-tablet drug regimen that  
32 is as effective as a multitablet regimen unless, consistent with  
33 clinical guidelines and peer-reviewed scientific and medical  
34 literature, the multitablet regimen is clinically equally or more  
35 effective and more likely to result in adherence to a drug regimen.

36 ~~(2) No more than 50 percent of drugs approved by the United~~  
37 ~~States Food and Drug Administration (FDA) that are in the same~~  
38 ~~drug class may be assigned to the two highest cost tiers of a drug~~  
39 ~~formulary. All health care service plan formularies shall include~~  
40 ~~at least one drug in the lower cost tiers if all FDA-approved drugs~~

1 in the same drug class would otherwise qualify for the highest cost  
 2 tiers and at least three drugs in that class are available as  
 3 FDA-approved drugs. The drug or drugs assigned to the lower cost  
 4 tiers pursuant to this paragraph shall be the drug or drugs that were  
 5 most often prescribed during the immediately preceding plan year,  
 6 based on the health care service plan's experience.

7 (d)

8 (e) (1) With respect to an individual or group health care service  
 9 plan contract subject to Section 1367.006, the copayment,  
 10 coinsurance, or any other form of cost sharing for a covered  
 11 outpatient prescription drug for an individual prescription for a  
 12 supply of up to 30 days shall not exceed two hundred fifty dollars  
 13 (\$250), except as provided in paragraphs (2) and (3).

14 (2) With respect to products with actuarial value at, or equivalent  
 15 to, the bronze level, cost sharing for a covered outpatient  
 16 prescription drug for an individual prescription for a supply of up  
 17 to 30 days shall not exceed five hundred dollars-(\$500)- (\$500),  
 18 *except as provided in paragraph (3).*

19 (3) For a health care service plan contract that is a "high  
 20 deductible health plan" under the definition set forth in Section  
 21 223(c)(2) of Title 26 of the United States Code, ~~paragraph~~  
 22 *paragraphs (1) and (2) of this subdivision shall apply only once*  
 23 *an enrollee's deductible has been satisfied for the year.*

24 (4) *For a nongrandfathered individual or small group health*  
 25 *care service plan contract, the deductible for outpatient drugs, if*  
 26 *any, shall not exceed twice the amount specified in paragraph (1)*  
 27 *or (2), respectively.*

28 (5) *For purposes of paragraphs (1) and (2), "any other form*  
 29 *of cost sharing" shall not include deductible.*

30 (e)

31 (f) (1) If a health care service plan contract maintains a drug  
 32 formulary grouped into tiers that includes a fourth tier or specialty  
 33 tier, a health care service plan contract shall use the following  
 34 definitions for each tier of the drug formulary:

35 (A) Tier one shall consist of most generic drugs and low-cost  
 36 low-cost preferred brand *name* drugs.

37 (B) Tier two shall consist of nonpreferred generic drugs,  
 38 preferred brand name drugs, and any other drugs recommended  
 39 by the health care service plan's pharmacy and therapeutics  
 40 committee based on safety and efficacy and not solely based on

1 ~~the cost of the prescription drug, and which generally have a~~  
2 ~~preferred and often less costly therapeutic alternative at a lower~~  
3 ~~tier. *safety, efficacy, and cost.*~~

4 (C) Tier three shall consist of nonpreferred brand name drugs  
5 *or drugs* that are recommended by the health care service plan's  
6 pharmacy and therapeutics committee based on ~~safety and efficacy~~  
7 ~~and not solely based on the cost of the prescription drug. *safety,*~~  
8 *efficacy, and cost, or that generally have a preferred and often*  
9 *less costly therapeutic alternative at a lower tier.*

10 (D) Tier four shall consist of drugs that are biologics, drugs that  
11 the FDA or the manufacturer requires to be distributed through a  
12 specialty pharmacy, drugs that require the enrollee to have special  
13 training or clinical monitoring for self-administration, or drugs  
14 that cost the health plan more than six hundred dollars (\$600) net  
15 ~~of rebates. *rebates for a one-month supply.*~~

16 (2) ~~This section does not require a health care service plan~~  
17 ~~contract to include a fourth tier. A health care service plan contract~~  
18 ~~may maintain a drug formulary with fewer than four tiers.~~

19 (3) *This section shall not be construed to limit a health care*  
20 *service plan from placing any drug in a lower tier.*

21 ~~(f)~~

22 (g) A health care service plan contract shall ensure that the  
23 placement of prescription drugs on formulary tiers is based on  
24 clinically indicated, reasonable medical management practices.

25 ~~(g)~~

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

31 ~~(h)~~

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

38 (j) *In the provision of outpatient prescription drug coverage, a*  
39 *health care service plan may utilize formulary, prior authorization,*

1 *step therapy, or other reasonable medical management practices*  
 2 *consistent with this chapter.*

3 *(k) This section shall not apply to a health care service plan*  
 4 *that contracts with the State Department of Health Care Services.*

5 (i)

6 *(l) This section shall remain in effect only until January 1, 2021,*  
 7 *2020, and as of that date is repealed, unless a later enacted statute,*  
 8 *that is enacted before January 1, 2021, 2020, deletes or extends*  
 9 *that date.*

10 SEC. 2. Section 1342.71 is added to the Health and Safety  
 11 Code, to read:

12 1342.71. (a) The Legislature hereby finds and declares all of  
 13 the following:

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

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

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

30 ~~(b) A nongrandfathered group health care service plan contract~~  
 31 ~~that is offered, amended, or renewed on or after July 1, 2016, shall~~  
 32 ~~comply with this section. A nongrandfathered individual health~~  
 33 ~~care service plan contract that is offered, amended, or renewed on~~  
 34 ~~or after January 1, 2017, shall comply with this section. The~~  
 35 ~~cost-sharing limits established by this section apply only to~~  
 36 ~~outpatient prescription drugs covered by the contract that constitute~~  
 37 ~~essential health benefits, as defined in Section 1367.005. This~~  
 38 ~~section does not apply to Medi-Cal managed care contracts.~~

39 *(c) (1) A health care service plan contract that provides*  
 40 *coverage for outpatient prescription drugs shall cover medically*

1 *necessary prescription drugs, including nonformulary drugs*  
2 *determined to be medically necessary consistent with this chapter.*

3 *(2) If a nonformulary drug is authorized consistent with this*  
4 *chapter, the cost sharing shall be the same as for a formulary drug.*

5 ~~(e)~~

6 ~~(d) (1) Consistent with federal law and guidance, and~~  
7 ~~notwithstanding Section 1342.7 and any regulations adopted~~  
8 ~~pursuant to that section, guidance, the formulary or formularies~~  
9 ~~for outpatient prescription drugs maintained by the health care~~  
10 ~~service plan shall not discourage the enrollment of individuals~~  
11 ~~with health conditions and shall not reduce the generosity of the~~  
12 ~~benefit for enrollees with a particular condition. condition in a~~  
13 ~~manner that is not based on a clinical indication or reasonable~~  
14 ~~medical management practices. Section 1342.7 and any regulations~~  
15 ~~adopted pursuant to that section shall be interpreted in a manner~~  
16 ~~that is consistent with this section.~~

17 ~~(1)~~

18 ~~(2) For combination antiretroviral drug treatments that are~~  
19 ~~medically necessary for the treatment of AIDS/HIV, a health care~~  
20 ~~service plan contract shall cover a single-tablet drug regimen that~~  
21 ~~is as effective as a multitablet regimen unless, consistent with~~  
22 ~~clinical guidelines and peer-reviewed scientific and medical~~  
23 ~~literature, the multitablet regimen is clinically equally or more~~  
24 ~~effective and more likely to result in adherence to a drug regimen.~~

25 ~~(2) No more than 50 percent of drugs approved by the United~~  
26 ~~States Food and Drug Administration (FDA) that are in the same~~  
27 ~~drug class may be assigned to the two highest cost tiers of a drug~~  
28 ~~formulary. All health care service plan formularies shall include~~  
29 ~~at least one drug in the lower cost tiers if all FDA-approved drugs~~  
30 ~~in the same drug class would otherwise qualify for the highest cost~~  
31 ~~tiers and at least three drugs in that class are available as~~  
32 ~~FDA-approved drugs. The drug or drugs assigned to the lower cost~~  
33 ~~tiers pursuant to this paragraph shall be the drug or drugs that were~~  
34 ~~most often prescribed during the immediately preceding plan year,~~  
35 ~~based on the health care service plan's experience.~~

36 ~~(d) (1) If a health care service plan contract maintains a drug~~  
37 ~~formulary grouped into tiers that includes a fourth tier or specialty~~  
38 ~~tier, a health care service plan contract shall use the following~~  
39 ~~definitions for each tier of the drug formulary:~~

1 ~~(A) Tier one shall consist of most generic drugs and low cost~~  
2 ~~preferred brand drugs.~~

3 ~~(B) Tier two shall consist of nonpreferred generic drugs,~~  
4 ~~preferred brand name drugs, and any other drugs recommended~~  
5 ~~by the health care service plan's pharmacy and therapeutics~~  
6 ~~committee based on safety and efficacy and not solely based on~~  
7 ~~the cost of the prescription drug, and which generally have a~~  
8 ~~preferred and often less costly therapeutic alternative at a lower~~  
9 ~~tier.~~

10 ~~(C) Tier three shall consist of nonpreferred brand name drugs~~  
11 ~~that are recommended by the health care service plan's pharmacy~~  
12 ~~and therapeutics committee based on safety and efficacy and not~~  
13 ~~solely based on the cost of the prescription drug.~~

14 ~~(D) Tier four shall consist of drugs that are biologics, drugs that~~  
15 ~~the FDA or the manufacturer requires to be distributed through a~~  
16 ~~specialty pharmacy, drugs that require the enrollee to have special~~  
17 ~~training or clinical monitoring for self-administration, or drugs~~  
18 ~~that cost the health plan more than six hundred dollars (\$600) net~~  
19 ~~of rebates.~~

20 ~~(2) This section does not require a health care service plan~~  
21 ~~contract to include a fourth tier. A~~

22 ~~(e) (1) A health care service plan contract may maintain a drug~~  
23 ~~formulary with fewer than four tiers.~~

24 ~~(2) This section shall not be construed to limit a health care~~  
25 ~~service plan from placing any drug in a lower tier.~~

26 ~~(e)~~

27 ~~(f) A health care service plan contract shall ensure that the~~  
28 ~~placement of prescription drugs on formulary tiers is based on~~  
29 ~~clinically indicated, reasonable medical management practices.~~

30 ~~(f)~~

31 ~~(g) This section shall not be construed to require a health care~~  
32 ~~service plan to impose cost sharing. This section shall not be~~  
33 ~~construed to require cost sharing for prescription drugs that state~~  
34 ~~or federal law otherwise requires to be provided without cost~~  
35 ~~sharing.~~

36 ~~(g)~~

37 ~~(h) This section does not require or authorize a health care~~  
38 ~~service plan that contracts with the State Department of Health~~  
39 ~~Care Services to provide services to Medi-Cal beneficiaries to~~  
40 ~~provide coverage for prescription drugs that are not required~~

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

3 (i) *In the provision of outpatient prescription drug coverage, a*  
4 *health care service plan may utilize formulary, prior authorization,*  
5 *step therapy, or other reasonable medical management practices*  
6 *consistent with this chapter.*

7 (j) *This section shall not apply to a health care service plan that*  
8 *contracts with the State Department of Health Care Services.*

9 (h)

10 (k) This section shall become operative on January 1, ~~2021~~.  
11 2020.

12 ~~SEC. 3. Section 1367.24 of the Health and Safety Code is~~  
13 ~~amended to read:~~

14 ~~1367.24. (a) (1) Every health care service plan 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, 1999, every health care service plan that provides~~  
19 ~~prescription drug benefits shall file with the department a~~  
20 ~~description of its process for responding to authorization requests~~  
21 ~~for nonformulary drugs. Any changes to this process shall be filed~~  
22 ~~with the department pursuant to Section 1352. The plan shall~~  
23 ~~provide that the enrollee, the enrollee's designee, or the enrollee's~~  
24 ~~prescribing provider may seek an authorization for a nonformulary~~  
25 ~~prescription drug.~~

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

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

39 ~~(4) Each plan shall provide a written description of its most~~  
40 ~~current process to its prescribing providers. For purposes of this~~

1 section, a prescribing provider shall include a provider authorized  
2 to write a prescription, pursuant to subdivision (a) of Section 4040  
3 of the Business and Professions Code, to treat a medical condition  
4 of an enrollee.

5 (b) Any plan that disapproves a request made pursuant to  
6 subdivision (a) by a prescribing provider to obtain authorization  
7 for a nonformulary drug shall provide the reasons for the  
8 disapproval in a notice provided to the enrollee. The notice shall  
9 indicate that the enrollee may file a grievance with the plan if the  
10 enrollee objects to the disapproval, including any alternative drug  
11 or treatment offered by the plan. The notice shall comply with  
12 subdivision (b) of Section 1368.02.

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

18 (d) The process described in subdivision (a) by which enrollees  
19 may obtain medically necessary nonformulary drugs, including  
20 specified timelines for responding to prescribing provider  
21 authorization requests, shall be described in evidence of coverage  
22 and disclosure forms, as required by subdivision (a) of Section  
23 1363, issued on or after July 1, 1999.

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

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

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

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

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

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

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

20 ~~(i) (1) Nonformulary prescription drugs shall include any drug~~  
21 ~~for which an enrollee’s copayment or out-of-pocket costs are~~  
22 ~~different than the copayment for a formulary prescription drug,~~  
23 ~~except as otherwise provided by law or regulation or in cases in~~  
24 ~~which the drug has been excluded in the plan contract pursuant to~~  
25 ~~Section 1342.7.~~

26 ~~(2) If a nonformulary drug is authorized consistent with this~~  
27 ~~section, the cost sharing shall be the same as for a formulary drug~~  
28 ~~consistent with, until January 1, 2021, subdivision (d) of Section~~  
29 ~~1342.71.~~

30 ~~(j) Nothing in this section shall be construed to affect an~~  
31 ~~enrollee’s or subscriber’s eligibility to submit a grievance to the~~  
32 ~~department for review under Section 1368 or to apply to the~~  
33 ~~department for an independent medical review under Section~~  
34 ~~1370.4 or Article 5.55 (commencing with Section 1374.30) of this~~  
35 ~~chapter.~~

36 ~~(k) Nothing in this section shall be construed to restrict or impair~~  
37 ~~the application of any other provision of this chapter, including,~~  
38 ~~but not limited to, Section 1367, which includes among its~~  
39 ~~requirements that a health care service plan furnish services in a~~  
40 ~~manner providing continuity of care and demonstrate that medical~~

1 ~~decisions are rendered by qualified medical providers unhindered~~  
2 ~~by fiscal and administrative management.~~

3 ~~SEC. 4.~~

4 *SEC. 3.* Section 1367.41 is added to the Health and Safety  
5 Code, immediately following Section 1367.4, to read:

6 1367.41. (a) Commencing January 1, 2017, a ~~plan~~ *health care*  
7 *service plan* shall maintain a pharmacy and therapeutics committee  
8 that shall be responsible for developing, maintaining, and  
9 overseeing any drug formulary list. If the plan delegates  
10 responsibility for the formulary to any entity, the obligation of the  
11 plan to comply with this chapter shall not be waived.

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

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

16 (2) Consist of a majority of individuals who are practicing  
17 physicians, practicing pharmacists, and other practicing health  
18 professionals who are licensed to prescribe drugs.

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

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

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

29 (f) The pharmacy and therapeutics committee shall do all of the  
30 following:

31 (1) Develop and document procedures to ensure appropriate  
32 drug review and inclusion.

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

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

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

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

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

9 (7) Review new United States Food and Drug  
10 Administration-approved drugs and new uses for existing drugs.

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

16 (9) Ensure that 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 *(g) This section shall be interpreted consistent with federal*  
21 *guidance issued under paragraph (3) of subdivision (a) of Section*  
22 *156.122 of Title 45 of the Code of Federal Regulations. This section*  
23 *shall apply to the individual, small group, and large group markets.*

24 ~~SEC. 5.~~

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

27 1367.42. (a) ~~A~~For plan years commencing on or after January  
28 1, 2017, a plan that provides essential health benefits shall allow  
29 an enrollee to access prescription drug benefits at an in-network  
30 retail pharmacy unless the prescription drug is subject to restricted  
31 distribution by the United States Food and Drug Administration  
32 or requires special handling, provider coordination, or patient  
33 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. 6.~~

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~~ *cost-sharing* tiers and  
 36 utilization controls, including prior authorization or step therapy  
 37 requirements, 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. 7:~~

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~~ *cost-sharing* tiers and  
17 utilization controls, including prior authorization or step therapy  
18 requirements, 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. 8:~~

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 life,  
16 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  
27 individuals, and may result in lower adherence to a prescription  
28 drug treatment 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 (c) (1) A policy of health insurance that provides coverage for  
38 outpatient prescription drugs shall cover medically necessary  
39 prescription ~~drugs.~~ *drugs, including nonformulary drugs*  
40 *determined to be medically necessary consistent with this part.*

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 *(2) If a nonformulary drug is authorized consistent with this*  
5 *part, the cost sharing shall be the same as for a formulary drug.*

6 (d) Copayments, coinsurance, and other cost sharing for  
7 outpatient prescription drugs shall be reasonable so as to allow  
8 access to medically necessary outpatient prescription drugs.

9 (e) *(1) Consistent with federal law and guidance, the formulary*  
10 *or formularies for outpatient prescription drugs maintained by the*  
11 *health insurer shall not discourage the enrollment of individuals*  
12 *with health conditions and shall not reduce the generosity of the*  
13 *benefit for insureds with a particular—condition. condition in a*  
14 *manner that is not based on a clinical indication or reasonable*  
15 *medical management practices. Section 1342.7 of the Health and*  
16 *Safety Code and any regulations adopted pursuant to that section*  
17 *shall be interpreted in a manner that is consistent with this section.*

18 ~~(1)~~

19 (2) For combination antiretroviral drug treatments that are  
20 medically necessary for the treatment of AIDS/HIV, a policy of  
21 health insurance shall cover a single-tablet drug regimen that is as  
22 effective as a multitablet regimen unless, consistent with clinical  
23 guidelines and peer-reviewed scientific and medical literature, the  
24 multitablet regimen is clinically equally or more effective and  
25 more likely to result in adherence to a drug regimen.

26 ~~(2) No more than 50 percent of drugs approved by the United~~  
27 ~~States Food and Drug Administration (FDA) that are in the same~~  
28 ~~drug class may be assigned to the two highest cost tiers of a drug~~  
29 ~~formulary. All health insurer formularies shall include at least one~~  
30 ~~drug in the lower cost tiers if all FDA-approved drugs in the same~~  
31 ~~drug class would otherwise qualify for the highest cost tiers and~~  
32 ~~at least three drugs in that class are available as FDA-approved~~  
33 ~~drugs. The drug or drugs assigned to the lower cost tiers pursuant~~  
34 ~~to this paragraph shall be the drug or drugs that were most often~~  
35 ~~prescribed during the immediately preceding plan year, based on~~  
36 ~~the health insurer's experience.~~

37 (3) ~~A health insurer shall demonstrate to the commissioner that~~  
38 ~~any~~ *Any limitation or utilization management is shall be consistent*  
39 *with and based on clinical guidelines and peer-reviewed scientific*  
40 *and medical literature.*

1 (f) (1) With respect to an individual or group policy of health  
2 insurance subject to Section 10112.28, the copayment, coinsurance,  
3 or any other form of cost sharing for a covered outpatient  
4 prescription drug for an individual prescription for a supply of up  
5 to 30 days shall not exceed two hundred fifty dollars (\$250), except  
6 as provided in paragraphs (2) and (3).

7 (2) With respect to products with actuarial value at or equivalent  
8 to the bronze level, cost sharing for a covered outpatient  
9 prescription drug for an individual prescription for a supply of up  
10 to 30 days shall not exceed five hundred dollars ~~(\$500)~~. (\$500),  
11 *except as provided in paragraph (3)*.

12 (3) For a policy of health insurance that is a “high deductible  
13 health plan” under the definition set forth in Section 223(c)(2) of  
14 Title 26 of the United States Code, ~~paragraph paragraphs (1) and~~  
15 (2) of this subdivision shall apply only once an insured’s deductible  
16 has been satisfied for the year.

17 (4) *For a nongrandfathered individual or small group policy*  
18 *of health insurance, the deductible for outpatient drugs, if any,*  
19 *shall not exceed twice the amount specified in paragraph (1) or*  
20 *(2), respectively.*

21 (5) *For purposes of paragraphs (1) and (2), “any other form*  
22 *of cost sharing” shall not include deductible.*

23 (g) (1) If a policy of health insurance maintains a drug  
24 formulary grouped into tiers that includes a fourth-tier or specialty  
25 tier, a policy of health insurance shall use the following definitions  
26 for each tier of the drug formulary:

27 (A) Tier one shall consist of most generic drugs and low-cost  
28 preferred brand *name* drugs.

29 (B) Tier two shall consist of nonpreferred generic drugs,  
30 preferred brand name drugs, and any other drugs recommended  
31 by the health insurer’s pharmacy and therapeutics committee based  
32 on ~~safety and efficacy and not solely based on the cost of the~~  
33 ~~prescription drug.~~ *safety, efficacy, and cost.*

34 (C) Tier three shall consist of nonpreferred brand name drugs  
35 *or drugs* that are recommended by the health insurer’s pharmacy  
36 and therapeutics committee based on ~~safety and efficacy and not~~  
37 ~~solely based on the cost of the prescription drug,~~ and which *safety,*  
38 *efficacy, and cost, or that* generally have a preferred and often less  
39 costly therapeutic alternative at a lower tier.

1 (D) Tier four shall consist of drugs that are biologics, drugs that  
 2 the FDA or the manufacturer requires to be distributed through a  
 3 specialty pharmacy, drugs that require the insured to have special  
 4 training or clinical monitoring for self-administration, or drugs  
 5 that cost the health insurer more than six hundred dollars (\$600)  
 6 net of ~~rebates~~. *rebates for a one-month supply.*

7 (2) ~~This section does not require a policy of health insurance to~~  
 8 ~~include a fourth tier.~~ A policy of health insurance may maintain a  
 9 drug formulary with fewer than four tiers.

10 (3) *This section shall not be construed to limit a health insurer*  
 11 *from placing any drug in a lower tier.*

12 (h) This section shall not be construed to require a health insurer  
 13 to impose cost sharing. This section shall not be construed to  
 14 require cost sharing for prescription drugs that state or federal law  
 15 otherwise requires to be provided without cost sharing.

16 (i) A policy of health insurance shall ensure that the placement  
 17 of prescription drugs on formulary tiers is based on clinically  
 18 indicated, reasonable medical management practices.

19 (j) *In the provision of outpatient prescription drug coverage, a*  
 20 *health insurer may utilize formulary, prior authorization, step*  
 21 *therapy, or other reasonable medical management practices*  
 22 *consistent with this part.*

23 (j)  
 24 (k) This section shall remain in effect only until January 1, ~~2021~~,  
 25 2020, and as of that date is repealed, unless a later enacted statute,  
 26 that is enacted before January 1, ~~2021~~, 2020, deletes or extends  
 27 that date.

28 ~~SEC. 9.~~

29 *SEC. 8.* Section 10123.193 is added to the Insurance Code, to  
 30 read:

31 10123.193. (a) The Legislature hereby finds and declares all  
 32 of the following:

33 (1) The federal Patient Protection and Affordable Care Act, its  
 34 implementing regulations and guidance, and related state law  
 35 prohibit discrimination based on a person's expected length of life,  
 36 present or predicted disability, degree of medical dependency,  
 37 quality of life, or other health conditions, including benefit designs  
 38 that have the effect of discouraging the enrollment of individuals  
 39 with significant health needs.

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

5 (3) Assignment of all or most prescription medications that treat  
6 a specific medical condition to the highest cost tiers of a formulary  
7 may effectively discourage enrollment by chronically ill  
8 individuals, and may result in lower adherence to a prescription  
9 drug treatment regimen.

10 (b) ~~A nongrandfathered group policy of health insurance that~~  
11 ~~is offered, amended, or renewed on or after July 1, 2016, shall~~  
12 ~~comply with this section. A nongrandfathered individual policy~~  
13 ~~of health insurance that is offered, amended, or renewed on or after~~  
14 ~~January 1, 2017, shall comply with this section. The cost-sharing~~  
15 ~~limits established by this section apply only to outpatient~~  
16 ~~prescription drugs covered by the policy that constitute essential~~  
17 ~~health benefits, as defined by Section 10112.27.~~

18 (c) (1) A policy of health insurance that provides coverage for  
19 outpatient prescription drugs shall cover medically necessary  
20 prescription ~~drugs:~~ *drugs, including nonformulary drugs*  
21 *determined to be medically necessary consistent with this part.*

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

25 *(2) If a nonformulary drug is authorized consistent with this*  
26 *part, the cost sharing shall be the same as for a formulary drug.*

27 (d) Copayments, coinsurance, and other cost sharing for  
28 outpatient prescription drugs shall be reasonable so as to allow  
29 access to medically necessary outpatient prescription drugs.

30 (e) (1) Consistent with federal law and guidance, the formulary  
31 or formularies for outpatient prescription drugs maintained by the  
32 health insurer shall not discourage the enrollment of individuals  
33 with health conditions and shall not reduce the generosity of the  
34 benefit for insureds with a particular ~~condition:~~ *condition in a*  
35 *manner that is not based on a clinical indication or reasonable*  
36 *medical management practices. Section 1342.7 of the Health and*  
37 *Safety Code and any regulations adopted pursuant to that section*  
38 *shall be interpreted in a manner that is consistent with this section.*

39 (†)

1 (2) For combination antiretroviral drug treatments that are  
2 medically necessary for the treatment of AIDS/HIV, a policy of  
3 health insurance shall cover a single-tablet drug regimen that is as  
4 effective as a multitablet regimen unless, consistent with clinical  
5 guidelines and peer-reviewed scientific and medical literature, the  
6 multitablet regimen is clinically equally or more effective and  
7 more likely to result in adherence to a drug regimen.

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

19 ~~(3) A health insurer shall demonstrate to the commissioner~~  
20 ~~that any~~

21 ~~(3) Any limitation or utilization management is shall be~~  
22 ~~consistent with and based on clinical guidelines and peer-reviewed~~  
23 ~~scientific and medical literature.~~

24 ~~(f) (1) If a policy of health insurance maintains a drug formulary~~  
25 ~~grouped into tiers that includes a fourth tier or specialty tier, a~~  
26 ~~policy of health insurance shall use the following definitions for~~  
27 ~~each tier of the drug formulary:~~

28 ~~(A) Tier one shall consist of most generic drugs and low-cost~~  
29 ~~preferred brand drugs.~~

30 ~~(B) Tier two shall consist of nonpreferred generic drugs,~~  
31 ~~preferred brand name drugs, and any other drugs recommended~~  
32 ~~by the health insurer's pharmacy and therapeutics committee based~~  
33 ~~on safety and efficacy and not solely based on the cost of the~~  
34 ~~prescription drug.~~

35 ~~(C) Tier three shall consist of nonpreferred brand name drugs~~  
36 ~~that are recommended by the health insurer's pharmacy and~~  
37 ~~therapeutics committee based on safety and efficacy and not solely~~  
38 ~~based on the cost of the prescription drug, and which generally~~  
39 ~~have a preferred and often less costly therapeutic alternative at a~~  
40 ~~lower tier.~~

1 ~~(D) Tier four shall consist of drugs that are biologics, drugs that~~  
2 ~~the FDA or the manufacturer requires to be distributed through a~~  
3 ~~specialty pharmacy, drugs that require the insured to have special~~  
4 ~~training or clinical monitoring for self-administration, or drugs~~  
5 ~~that cost the health insurer more than six hundred dollars (\$600)~~  
6 ~~net of rebates.~~

7 ~~(2) This section does not require a policy of health insurance to~~  
8 ~~include a fourth tier. A~~

9 ~~(f) (1) A policy of health insurance may maintain a drug~~  
10 ~~formulary with fewer than four tiers.~~

11 ~~(2) This section shall not be construed to limit a health insurer~~  
12 ~~from placing any drug in a lower tier.~~

13 ~~(g) This section shall not be construed to require a health insurer~~  
14 ~~to impose cost sharing. This section shall not be construed to~~  
15 ~~require cost sharing for prescription drugs that state or federal law~~  
16 ~~otherwise requires to be provided without cost sharing.~~

17 ~~(h) A policy of health insurance shall ensure that the placement~~  
18 ~~of prescription drugs on formulary tiers is based on clinically~~  
19 ~~indicated, reasonable medical management practices.~~

20 ~~(i) In the provision of outpatient prescription drug coverage, a~~  
21 ~~health insurer may utilize formulary, prior authorization, step~~  
22 ~~therapy, or other reasonable medical management practices~~  
23 ~~consistent with this part.~~

24 ~~(i)~~

25 ~~(j) This section shall become operative on January 1, 2021.~~  
26 ~~2020.~~

27 ~~SEC. 10.~~

28 ~~SEC. 9.~~ Section 10123.201 is added to the Insurance Code, to  
29 read:

30 10123.201. ~~(a) (1) Every health insurer that provides~~  
31 ~~prescription drug benefits shall maintain an expeditious process~~  
32 ~~by which prescribing providers may obtain authorization for a~~  
33 ~~medically necessary nonformulary prescription drug. On or before~~  
34 ~~July 1, 2016, every insurer that provides prescription drug benefits~~  
35 ~~shall file with the commissioner a description of its process for~~  
36 ~~responding to authorization requests for nonformulary drugs. Any~~  
37 ~~changes to this process shall be filed with the commissioner. The~~  
38 ~~insurer shall provide that the insured, the insured's designee, or~~  
39 ~~the insured's prescribing provider may seek an authorization for~~  
40 ~~a nonformulary prescription drug. A policy of health insurance~~

1 *that covers outpatient prescription drugs shall cover medically*  
2 *necessary drugs. The policy may provide for step therapy and prior*  
3 *authorization consistent with Section 1342.7 of the Health and*  
4 *Safety Code and any regulations adopted pursuant to that section.*

5 ~~(2) Each insurer shall respond to an authorization request within~~  
6 ~~72 hours following receipt of the authorization request for a~~  
7 ~~nonurgent authorization. If the insurer grants the authorization~~  
8 ~~request, the insurer shall provide coverage of the nonformulary~~  
9 ~~drug for the duration of the prescription, including refills.~~

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

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

26 ~~(5) Each insurer shall provide a written description of its most~~  
27 ~~current process 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 insured.~~

32 (b) Any insurer that disapproves a request made pursuant to  
33 subdivision (a) by a prescribing provider to obtain authorization  
34 for a nonformulary drug shall provide the reasons for the  
35 disapproval in a notice provided to the insured. The notice shall  
36 indicate that the insured may file a ~~grievance~~ *complaint* with the  
37 insurer if the insured objects to the disapproval, including any  
38 alternative drug or treatment offered by the insurer. The notice  
39 shall comply with Section 10133.661.

1 (c) (1) Commencing January 1, 2017, an insurer shall maintain  
2 a pharmacy and therapeutics committee that shall be responsible  
3 for developing, maintaining, and overseeing any drug formulary  
4 list. If the insurer delegates responsibility for the formulary to any  
5 entity, the obligation of the insurer to comply with this part shall  
6 not be waived.

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

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

11 (B) Consist of a majority of individuals who are practicing  
12 physicians, practicing pharmacists, and other practicing health  
13 professionals who are licensed to prescribe drugs.

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

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

20 (5) The pharmacy and therapeutics committee shall meet at least  
21 quarterly and shall maintain written documentation of the rationale  
22 for its decisions regarding the development of, or revisions to, the  
23 formulary drug list.

24 (6) The pharmacy and therapeutics committee shall do all of  
25 the following:

26 (A) Develop and document procedures to ensure appropriate  
27 drug review and inclusion.

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

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

34 (D) Review policies that guide exceptions and other utilization  
35 management processes, including drug utilization review, quantity  
36 limits, and therapeutic interchange.

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

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

4 (G) Review new United States Food and Drug  
5 Administration-approved drugs and new uses for existing drugs.

6 (H) Ensure the insurer’s formulary drug list or lists cover a range  
7 of drugs across a broad distribution of therapeutic categories and  
8 classes and recommended drug treatment regimens that treat all  
9 disease states and does not discourage enrollment by any group  
10 of insureds.

11 (I) Ensure the insurer’s formulary drug list or lists provide  
12 appropriate access to drugs that are included in broadly accepted  
13 treatment guidelines and that are indicative of general best practices  
14 at the time.

15 (7) *This subdivision shall be interpreted consistent with federal*  
16 *guidance issued under paragraph (3) of subdivision (a) of Section*  
17 *156.122 of Title 45 of the Code of Federal Regulations. This*  
18 *subdivision shall apply to the individual, small group, and large*  
19 *group markets.*

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

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

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

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

5 (4) ~~An~~ *For plan years commencing on or after January 1, 2017,*  
6 *an* insurer that provides essential health benefits shall allow an  
7 insured to access prescription drug benefits at an in-network retail  
8 pharmacy unless the prescription drug is subject to restricted  
9 distribution by the United States Food and Drug Administration  
10 or requires special handling, provider coordination, or patient  
11 education that cannot be provided by a retail pharmacy. An insurer  
12 that provides essential health benefits may charge an insured a  
13 different cost sharing for obtaining a covered drug at a retail  
14 pharmacy, but all cost sharing shall count toward the policy's  
15 annual limitation on cost sharing consistent with Section 10112.28.

16 ~~(e) The process described in subdivision (a) by which insureds~~  
17 ~~may obtain medically necessary nonformulary drugs, including~~  
18 ~~specified timelines for responding to prescribing provider~~  
19 ~~authorization requests, shall be described in evidence of coverage~~  
20 ~~and disclosure forms, as required by Section 10603, issued on or~~  
21 ~~after January 1, 2016.~~

22 (f)

23 (e) Every health insurer that provides prescription drug benefits  
24 shall maintain all of the following information, which shall be  
25 made available to the commissioner upon request:

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

31 (2) Records developed by the pharmacy and therapeutic  
32 committee of the insurer, 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 insureds of the insurer, that fully describe the reasoning  
37 behind formulary decisions.

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

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

4 ~~(g)~~

5 (f) If an insurer provides prescription drug benefits, the  
6 commissioner shall, as part of its market conduct examination,  
7 review the performance of the insurer in providing those benefits,  
8 including, but not limited to, a review of the procedures and  
9 information maintained pursuant to this section, and describe the  
10 performance of the insurer as part of its report issued as part of its  
11 market conduct examination.

12 ~~(h)~~

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

16 ~~(i)~~

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

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

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

25 ~~(j)~~

26 (i) (1) Nonformulary prescription drugs shall include any drug  
27 for which an insured's copayment or out-of-pocket costs are  
28 different than the copayment for a formulary prescription drug,  
29 except as otherwise provided by law or regulation.

30 (2) If a nonformulary drug is authorized consistent with this  
31 section, the cost sharing shall be the same as for a formulary drug  
32 consistent with, until January 1, ~~2021~~, 2020, subdivision (f) of  
33 Section 10123.193.

34 ~~(k)~~

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

40 ~~(l)~~

1 (k) Nothing in this section shall be construed to restrict or impair  
2 the application of any other provision of this part.

3 ~~SEC. 11.~~

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

O