

**Introduced by Senator Wiener  
(Principal coauthor: Senator Atkins)**

February 7, 2018

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An act to amend and repeal Section 1342.71 of the Health and Safety Code, and to amend and repeal Section 10123.193 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1021, as introduced, Wiener. 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 prohibits 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. Existing law, until January 1, 2020, provides 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. Existing law, until January 1, 2020, requires a nongrandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary.

This bill would extend those provisions indefinitely. The bill would prohibit a drug formulary maintained by a health care service plan or health insurer from containing more than 4 tiers, and would permit a biologic with a therapeutic equivalent to be placed on a tier other than

tier 4, as specified. The bill would require a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy’s retail price is less than the applicable copayment or coinsurance amount.

Existing law requires 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.

This bill would extend that coverage requirement to combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, as specified. Because a willful violation of the bill’s requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

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

- 1 SECTION 1. Section 1342.71 of the Health and Safety Code,
- 2 as amended by Section 175 of Chapter 86 of the Statutes of 2016,
- 3 is amended to read:
- 4 1342.71. (a) The Legislature hereby finds and declares all of
- 5 the following:
- 6 (1) The federal Patient Protection and Affordable Care Act, its
- 7 implementing regulations and guidance, and related state law
- 8 prohibit discrimination based on a person’s expected length of life,
- 9 present or predicted disability, degree of medical dependency,
- 10 quality of life, or other health conditions, including benefit designs
- 11 that have the effect of discouraging the enrollment of individuals
- 12 with significant health needs.
- 13 (2) The Legislature intends to build on existing state and federal
- 14 law to ensure that health coverage benefit designs do not have an
- 15 unreasonable discriminatory impact on chronically ill individuals,
- 16 and to ensure affordability of outpatient prescription drugs.
- 17 (3) Assignment of all or most prescription medications that treat
- 18 a specific medical condition to the highest cost tiers of a formulary

1 may effectively discourage enrollment by chronically ill  
2 individuals, and may result in lower adherence to a prescription  
3 drug treatment regimen.

4 (b) A nongrandfathered health care service plan contract that is  
5 offered, amended, or renewed on or after January 1, 2017, shall  
6 comply with this section. The cost-sharing limits established by  
7 this section apply only to outpatient prescription drugs covered by  
8 the contract that constitute essential health benefits, as defined in  
9 Section 1367.005.

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

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

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

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

37 (2) With respect to products with actuarial value at, or equivalent  
38 to, the bronze level, cost sharing for a covered outpatient  
39 prescription drug for an individual prescription for a supply of up

1 to 30 days shall not exceed five hundred dollars (\$500), except as  
2 provided in paragraph (3).

3 (3) For a health care service plan contract that is a “high  
4 deductible health plan” under the definition set forth in Section  
5 223(c)(2) of Title 26 of the United States Code, paragraphs (1)  
6 and (2) of this subdivision shall apply only once an enrollee’s  
7 deductible has been satisfied for the year.

8 (4) For a nongrandfathered individual or small group health  
9 care service plan contract, the annual deductible for outpatient  
10 drugs, if any, shall not exceed twice the amount specified in  
11 paragraph (1) or (2), respectively.

12 (5) For purposes of paragraphs (1) and (2), “any other form of  
13 cost sharing” shall not include a deductible.

14 (f) (1) If a health care service plan contract for a  
15 nongrandfathered individual or small group product maintains a  
16 drug formulary grouped into tiers that includes a fourth tier, a  
17 health care service plan contract shall use the following definitions  
18 for each tier of the drug formulary:

19 (A) Tier one shall consist of most generic drugs and low-cost  
20 preferred brand name drugs.

21 (B) Tier two shall consist of nonpreferred generic drugs,  
22 preferred brand name drugs, and any other drugs recommended  
23 by the health care service plan’s pharmacy and therapeutics  
24 committee based on safety, efficacy, and cost.

25 (C) Tier three shall consist of nonpreferred brand name drugs  
26 or drugs that are recommended by the health care service plan’s  
27 pharmacy and therapeutics committee based on safety, efficacy,  
28 and cost, or that generally have a preferred and often less costly  
29 therapeutic alternative at a lower tier.

30 (D) Tier four shall consist of drugs that are biologics, drugs that  
31 the FDA or the manufacturer requires to be distributed through a  
32 specialty pharmacy, drugs that require the enrollee to have special  
33 training or clinical monitoring for self-administration, or drugs  
34 that cost the health plan more than six hundred dollars (\$600) net  
35 of rebates for a one-month supply.

36 (2) In placing specific drugs on specific tiers, or choosing to  
37 place a drug on the formulary, the health care service plan shall  
38 take into account the other provisions of this section and this  
39 chapter.

1 (3) A health care service plan contract may maintain a drug  
2 formulary with fewer than four tiers. *A health care service plan*  
3 *contract shall not maintain a drug formulary with more than four*  
4 *tiers.*

5 (4) This section shall not be construed to limit a health care  
6 service plan from placing any drug in a lower tier. *If a biologic*  
7 *has a therapeutic equivalent, consistent with state law, it may be*  
8 *placed on a tier other than tier four.*

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

12 (h) (1) This section shall not be construed to require a health  
13 care service plan to impose cost sharing. ~~This~~

14 (2) *This* section shall not be construed to require cost sharing  
15 for prescription drugs that state or federal law otherwise requires  
16 to be provided without cost sharing.

17 (3) *A plan's prescription drug benefit shall provide that if the*  
18 *pharmacy's retail price for a prescription drug is less than the*  
19 *applicable copayment or coinsurance amount, the enrollee shall*  
20 *not be required to pay more than the retail price.*

21 ~~(i) This section does not require or authorize a health care~~  
22 ~~service plan that contracts with the State Department of Health~~  
23 ~~Care Services to provide services to Medi-Cal beneficiaries to~~  
24 ~~provide coverage for prescription drugs that are not required~~  
25 ~~pursuant to those programs or contracts, or to limit or exclude any~~  
26 ~~prescription drugs that are required by those programs or contracts.~~

27 ~~(j)~~

28 (i) In the provision of outpatient prescription drug coverage, a  
29 health care service plan may utilize formulary, prior authorization,  
30 step therapy, or other reasonable medical management practices  
31 consistent with this chapter.

32 ~~(k)~~

33 (j) This section does not apply to a health care service plan that  
34 contracts with the State Department of Health Care Services.

35 ~~(l) This section shall remain in effect only until January 1, 2020,~~  
36 ~~and as of that date is repealed, unless a later enacted statute, that~~  
37 ~~is enacted before January 1, 2020, deletes or extends that date.~~

38 SEC. 2. Section 1342.71 of the Health and Safety Code, as  
39 added by Section 2 of Chapter 619 of the Statutes of 2015, is  
40 repealed.

1     ~~1342.71. (a) The Legislature hereby finds and declares all of~~  
2 ~~the following:~~

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

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

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

19     ~~(b) A nongrandfathered health care service plan contract that is~~  
20 ~~offered, amended, or renewed on or after January 1, 2017, shall~~  
21 ~~comply with this section.~~

22     ~~(c) A health care service plan contract that provides coverage~~  
23 ~~for outpatient prescription drugs shall cover medically necessary~~  
24 ~~prescription drugs, including nonformulary drugs determined to~~  
25 ~~be medically necessary consistent with this chapter.~~

26     ~~(d) (1) Consistent with federal law and guidance, the formulary~~  
27 ~~or formularies for outpatient prescription drugs maintained by the~~  
28 ~~health care service plan shall not discourage the enrollment of~~  
29 ~~individuals with health conditions and shall not reduce the~~  
30 ~~generosity of the benefit for enrollees with a particular condition~~  
31 ~~in a manner that is not based on a clinical indication or reasonable~~  
32 ~~medical management practices. Section 1342.7 and any regulations~~  
33 ~~adopted pursuant to that section shall be interpreted in a manner~~  
34 ~~that is consistent with this section.~~

35     ~~(2) For combination antiretroviral drug treatments that are~~  
36 ~~medically necessary for the treatment of AIDS/HIV, a health care~~  
37 ~~service plan contract shall cover a single-tablet drug regimen that~~  
38 ~~is as effective as a multitablet regimen unless, consistent with~~  
39 ~~clinical guidelines and peer-reviewed scientific and medical~~

1 literature, the multitablet regimen is clinically equally or more  
2 effective and more likely to result in adherence to a drug regimen.

3 ~~(e) A health care service plan contract shall ensure that the~~  
4 ~~placement of prescription drugs on formulary tiers is based on~~  
5 ~~clinically indicated, reasonable medical management practices.~~

6 ~~(f) This section shall not be construed to require a health care~~  
7 ~~service plan to impose cost sharing. This section shall not be~~  
8 ~~construed to require cost sharing for prescription drugs that state~~  
9 ~~or federal law otherwise requires to be provided without cost~~  
10 ~~sharing.~~

11 ~~(g) This section does not require or authorize a health care~~  
12 ~~service plan that contracts with the State Department of Health~~  
13 ~~Care Services to provide services to Medi-Cal beneficiaries to~~  
14 ~~provide coverage for prescription drugs that are not required~~  
15 ~~pursuant to those programs or contracts, or to limit or exclude any~~  
16 ~~prescription drugs that are required by those programs or contracts.~~

17 ~~(h) In the provision of outpatient prescription drug coverage, a~~  
18 ~~health care service plan may utilize formulary, prior authorization,~~  
19 ~~step therapy, or other reasonable medical management practices~~  
20 ~~consistent with this chapter.~~

21 ~~(i) This section shall not apply to a health care service plan that~~  
22 ~~contracts with the State Department of Health Care Services.~~

23 ~~(j) This section shall become operative on January 1, 2020.~~

24 SEC. 3. Section 10123.193 of the Insurance Code, as amended  
25 by Section 204 of Chapter 86 of the Statutes of 2016, is amended  
26 to read:

27 10123.193. (a) The Legislature hereby finds and declares all  
28 of the following:

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

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

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

6 (b) A nongrandfathered policy of health insurance that is offered,  
7 amended, or renewed on or after January 1, 2017, shall comply  
8 with this section. The cost-sharing limits established by this section  
9 apply only to outpatient prescription drugs covered by the policy  
10 that constitute essential health benefits, as defined by Section  
11 10112.27.

12 (c) A policy of health insurance that provides coverage for  
13 outpatient prescription drugs shall cover medically necessary  
14 prescription drugs, including nonformulary drugs determined to  
15 be medically necessary consistent with this part.

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

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

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

35 (3) Any limitation or utilization management shall be consistent  
36 with and based on clinical guidelines and peer-reviewed scientific  
37 and medical literature.

38 (f) (1) With respect to an individual or group policy of health  
39 insurance subject to Section 10112.28, the copayment, coinsurance,  
40 or any other form of cost sharing for a covered outpatient

1 prescription drug for an individual prescription for a supply of up  
2 to 30 days shall not exceed two hundred fifty dollars (\$250), except  
3 as provided in paragraphs (2) and (3).

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

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

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

18 (5) For purposes of paragraphs (1) and (2), “any other form of  
19 cost sharing” shall not include a deductible.

20 (g) (1) If a policy of health insurance offered, sold, or renewed  
21 in the nongrandfathered individual or small group market maintains  
22 a drug formulary grouped into tiers that includes a fourth tier, a  
23 policy of health insurance shall use the following definitions for  
24 each tier of the drug formulary:

25 (A) Tier one shall consist of most generic drugs and low-cost  
26 preferred brand name drugs.

27 (B) Tier two shall consist of nonpreferred generic drugs,  
28 preferred brand name drugs, and any other drugs recommended  
29 by the health insurer’s pharmacy and therapeutics committee based  
30 on safety, efficacy, and cost.

31 (C) Tier three shall consist of nonpreferred brand name drugs  
32 or drugs that are recommended by the health insurer’s pharmacy  
33 and therapeutics committee based on safety, efficacy, and cost, or  
34 that generally have a preferred and often less costly therapeutic  
35 alternative at a lower tier.

36 (D) Tier four shall consist of drugs that are biologics, drugs that  
37 the FDA or the manufacturer requires to be distributed through a  
38 specialty pharmacy, drugs that require the insured to have special  
39 training or clinical monitoring for self-administration, or drugs

1 that cost the health insurer more than six hundred dollars (\$600)  
2 net of rebates for a one-month supply.

3 (2) In placing specific drugs on specific tiers, or choosing to  
4 place a drug on the formulary, the insurer shall take into account  
5 the other provisions of this section and this part.

6 (3) A policy of health insurance may maintain a drug formulary  
7 with fewer than four tiers. *A policy of health insurance shall not*  
8 *maintain a drug formulary with more than four tiers.*

9 (4) This section shall not be construed to limit a health insurer  
10 from placing any drug in a lower tier. *If a biologic has a*  
11 *therapeutic equivalent, consistent with state law, it may be placed*  
12 *on a tier other than tier four.*

13 (h) (1) This section shall not be construed to require a health  
14 insurer to impose cost sharing. ~~This~~

15 (2) *This section shall not be construed to require cost sharing*  
16 *for prescription drugs that state or federal law otherwise requires*  
17 *to be provided without cost sharing.*

18 (3) *A prescription drug benefit shall provide that if the*  
19 *pharmacy’s retail price for a prescription drug is less than the*  
20 *applicable copayment or coinsurance amount, the insured shall*  
21 *not be required to pay more than the retail price.*

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

25 (j) In the provision of outpatient prescription drug coverage, a  
26 health insurer may utilize formulary, prior authorization, step  
27 therapy, or other reasonable medical management practices  
28 consistent with this part.

29 ~~(k) This section shall remain in effect only until January 1, 2020,~~  
30 ~~and as of that date is repealed, unless a later enacted statute, that~~  
31 ~~is enacted before January 1, 2020, deletes or extends that date.~~

32 SEC. 4. Section 10123.193 of the Insurance Code, as added  
33 by Section 8 of Chapter 619 of the Statutes of 2015, is repealed.

34 ~~10123.193. (a) The Legislature hereby finds and declares all~~  
35 ~~of the following:~~

36 ~~(1) The federal Patient Protection and Affordable Care Act, its~~  
37 ~~implementing regulations and guidance, and related state law~~  
38 ~~prohibit discrimination based on a person’s expected length of life,~~  
39 ~~present or predicted disability, degree of medical dependency,~~  
40 ~~quality of life, or other health conditions, including benefit designs~~

1 that have the effect of discouraging the enrollment of individuals  
2 with significant health needs.

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

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

12 ~~(b) A nongrandfathered policy of health insurance that is offered,  
13 amended, or renewed on or after January 1, 2017, shall comply  
14 with this section.~~

15 ~~(c) A policy of health insurance that provides coverage for  
16 outpatient prescription drugs shall cover medically necessary  
17 prescription drugs, including nonformulary drugs determined to  
18 be medically necessary consistent with this part.~~

19 ~~(d) Copayments, coinsurance, and other cost sharing for  
20 outpatient prescription drugs shall be reasonable so as to allow  
21 access to medically necessary outpatient prescription drugs.~~

22 ~~(e) (1) Consistent with federal law and guidance, the formulary  
23 or formularies for outpatient prescription drugs maintained by the  
24 health insurer shall not discourage the enrollment of individuals  
25 with health conditions and shall not reduce the generosity of the  
26 benefit for insureds with a particular condition in a manner that is  
27 not based on a clinical indication or reasonable medical  
28 management practices. Section 1342.7 of the Health and Safety  
29 Code and any regulations adopted pursuant to that section shall  
30 be interpreted in a manner that is consistent with this section.~~

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

38 ~~(3) Any limitation or utilization management shall be consistent  
39 with and based on clinical guidelines and peer-reviewed scientific  
40 and medical literature.~~

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

5     ~~(g) A policy of health insurance shall ensure that the placement~~  
6 ~~of prescription drugs on formulary tiers is based on clinically~~  
7 ~~indicated, reasonable medical management practices.~~

8     ~~(h) In the provision of outpatient prescription drug coverage, a~~  
9 ~~health insurer may utilize formulary, prior authorization, step~~  
10 ~~therapy, or other reasonable medical management practices~~  
11 ~~consistent with this part.~~

12     ~~(i) This section shall become operative on January 1, 2020.~~

13     SEC. 5. No reimbursement is required by this act pursuant to  
14 Section 6 of Article XIII B of the California Constitution because  
15 the only costs that may be incurred by a local agency or school  
16 district will be incurred because this act creates a new crime or  
17 infraction, eliminates a crime or infraction, or changes the penalty  
18 for a crime or infraction, within the meaning of Section 17556 of  
19 the Government Code, or changes the definition of a crime within  
20 the meaning of Section 6 of Article XIII B of the California  
21 Constitution.