SENATE BILL No. 1021

Introduced by Senator Wiener
(Principal coauthor: Senator Atkins)

February 7, 2018

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:

SECTION 1. Section 1342.71 of the Health and Safety Code, as amended by Section 175 of Chapter 86 of the Statutes of 2016, is amended to read:

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

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

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

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(j)~~

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

~~(k)~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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