AMENDED IN SENATE FEBRUARY 28, 2022

SENATE BILL No. 853

Introduced by Senator Wiener

January 19, 2022

An act to amend Sections 1367.21 and 1367.22 of, and to add Section 1367.28 to, the Health and Safety Code, and to amend Section 10123.195 of, and to add Section 10123.190 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 853, as amended, Wiener. Prescription drug coverage.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law generally authorizes a health care service plan or health insurer to use utilization review, under which a licensed physician or a licensed health care professional who is competent to evaluate specific clinical issues may approve, modify, delay, or deny requests for health care services based on medical necessity. Existing law prohibits a health care service plan contract that covers prescription drug benefits or a specified health insurance policy from limiting or excluding coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which it was approved by the federal Food and Drug Administration if specified conditions are met. Existing law also prohibits a health care service plan that covers prescription drug benefits from limiting or excluding coverage for a drug that was previously approved for coverage if an enrollee continues to be prescribed that drug, as specified.

This bill would expand the above-described prohibitions to prohibit limiting or excluding coverage of a dose of a ~~drug.~~ *drug or dosage form.* The bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits to provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during utilization review and any ~~appeals.~~ *appeals if that drug has been previously approved for a medical condition of the enrollee or insured and has been prescribed by a health care provider.* The bill would prohibit a plan or insurer from seeking reimbursement for that coverage if the final utilization review decision is to deny coverage for the prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

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 1367.21 of the Health and Safety Code is amended to read:

1367.21. (a) A health care service plan contract that covers prescription drug benefits shall not be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug or dose of a drug on the basis that the drug or dose of the drug is prescribed for a use or ~~dosage level~~ *dose* that is different from the use or ~~dosage level~~ *dose* for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) One of the following is true:

(A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition.

(B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously

debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) This section does not prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(h) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

(i) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

SEC. 2. Section 1367.22 of the Health and Safety Code is amended to read:

1367.22. (a) A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a ~~drug or~~ *drug,* dose of a ~~drug~~ *drug, or dosage form* for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the ~~drug or~~ *drug,* dose of the ~~drug~~ *drug, or dosage form* is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. This section does not preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, and does not prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) This section does not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. Coverage for different-use drugs is subject to Section 1367.21.

(c) This section does not apply to coverage for any drug that was denied in a final utilization review pursuant to Section 1367.28.

~~(c)~~

(d) This section shall not be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that plans furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

~~(d)~~

(e) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

SEC. 3. Section 1367.28 is added to the Health and Safety Code, to read:

1367.28. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits shall provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during the entire duration of utilization review and any appeals of utilization ~~review.~~ *review if that drug has been previously approved for coverage by a health care service plan for a medical condition of the enrollee and has been prescribed by a health care provider.*

(b) A health care service plan shall not seek reimbursement from an enrollee, health care provider, or other person for prescription drug coverage during utilization review if the final utilization review decision is to deny coverage for that prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

(c) For purposes of this section, "utilization review" means prospectively, retrospectively, or concurrently reviewing and approving, modifying, delaying, or denying, based in whole or in part on medical necessity, a request by a health care provider,

enrollee, or authorized representative of a provider or enrollee for coverage of a prescription drug.

SEC. 4. Section 10123.190 is added to the Insurance Code, to read:

10123.190. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits shall provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during the entire duration of utilization review and any appeals of utilization ~~review.~~ *review if that drug has been previously approved for coverage by a health insurer for a medical condition of the insured and has been prescribed by a health care provider.*

(b) A health insurer shall not seek reimbursement from an insured, health care provider, or other person for prescription drug coverage during utilization review if the final utilization review decision is to deny coverage for that prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

(c) For purposes of this section, "utilization review" means prospectively, retrospectively, or concurrently reviewing and approving, modifying, delaying, or denying, based in whole or in part on medical necessity, a request by a health care provider, insured, or authorized representative of a provider or insured for coverage of a prescription drug.

SEC. 5. Section 10123.195 of the Insurance Code is amended to read:

10123.195. (a) A group or individual disability insurance policy issued, delivered, or renewed in this state or certificate of group disability insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state that, as a provision of hospital, medical, or surgical services, directly or indirectly covers prescription drugs shall not limit or exclude coverage for a drug or dose of a drug on the basis that the drug or dose of the drug is prescribed for a use or ~~dosage level~~ *dose* that is different from the use or ~~dosage level~~ *dose* for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) One of the following is true:

(A) The drug is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition.

(B) The drug is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the insurer's formulary, if any.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

(g) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is located outside of California.

(h) This section does not prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(i) If an insurer denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under the Independent Medical Review System of Article 3.5 (commencing with Section 10169).

(j) This section is not applicable to vision-only, dental-only, Medicare or Champus supplement, disability income, long-term care, accident-only, specified disease or hospital confinement indemnity insurance.

SEC. 6. 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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