# SENATE BILL No. 621

**Introduced by Senator Caballero**

February 15, 2023

An act to amend Section 1367.206 of the Health and Safety Code, and to amend Section 10123.201 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 621, as introduced, Caballero. Health care coverage: biosimilar 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. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law authorizes a health care service plan or health insurer that provides coverage for prescription drugs to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition. Existing law does not prohibit a plan, insurer, or utilization review organization from requiring an enrollee or insured to try an AB-rated generic equivalent or interchangeable biological product before providing coverage for the equivalent branded prescription drug.

This bill would specify that a plan, insurer, or utilization review organization is also not prohibited from requiring an enrollee or insured to try a biosimilar before providing coverage for the equivalent branded prescription drug.

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

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

SECTION 1. Section 1367.206 of the Health and Safety Code is amended to read:

1367.206. (a) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a health care service plan that provides coverage for prescription drugs may require step therapy.

(b) A health care service plan shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 1367.241 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:

(1) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee in comparison to the requested prescription drug, based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(3) The enrollee has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health care service plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.

(4) The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider:

(A) Worsen a comorbid condition.

(B) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.

(C) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.

(5) The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.

(c) A health care provider or prescribing provider may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the health care service plan's current utilization management processes.

(d) An enrollee or the enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.

(e) This section does not prohibit either of the following:

(1) A health care service plan or utilization review organization from requiring an enrollee to try an AB-rated generic ~~equivalent~~ *equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code,* or interchangeable biological ~~product~~ *product, as defined in Section 262(i)(3) of Title 42 of the United States Code,* before providing coverage for the equivalent branded prescription drug.

(2) A health care provider from prescribing a prescription drug that is clinically appropriate.

(f) 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.

(g) For purposes of this section, "step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee.

(h) Commencing January 1, 2022, a health care service plan contract with a utilization review organization, medical group, or

other contracted entity that performs utilization review or utilization management functions on a health care service plan's behalf shall include terms that require the contracted entity to comply with this section and Section 1367.241.

SEC. 2. Section 10123.201 of the Insurance Code is amended to read:

10123.201. (a) A policy of health insurance that covers outpatient prescription drugs shall cover medically necessary drugs. The policy may provide for step therapy and prior authorization consistent with Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section.

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

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

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

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

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

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

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

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

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

(B) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing

peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.

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

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

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

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

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

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

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

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

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

(2) (A) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a health insurer may require step therapy.

(B) A health insurer shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 10123.191 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of

medically necessary covered services to the insured, taking into consideration the insured's needs and medical history, along with the professional judgment of the insured's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:

(i) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the insured in comparison to the requested prescription drug, based on the known clinical characteristics of the insured and the known characteristics and history of the insured's prescription drug regimen.

(ii) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics and history of the insured's prescription drug regimen.

(iii) The insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health insurer may require the submission of documentation demonstrating that the insured tried the required prescription drug before it was discontinued.

(iv) The required prescription drug is not clinically appropriate for the insured because the required drug is expected to do any of the following, as determined by the insured's prescribing provider:

(I) Worsen a comorbid condition.

(II) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.

(III) Pose a significant barrier to adherence to, or compliance with, the insured's drug regimen or plan of care.

(v) The insured is stable on a prescription drug selected by the insured's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.

(C) This section does not prohibit either of the following:

(i) An insurer or utilization review organization from requiring an insured to try an AB-rated generic ~~equivalent~~ *equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code,* or interchangeable biological ~~product~~ *product, as defined in Section 262(i)(3) of Title 42 of the United States Code,*

before providing coverage for the equivalent branded prescription drug.

(ii) A health care provider from prescribing a prescription drug that is clinically appropriate.

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

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

(d) A health care provider or prescribing provider may file an internal appeal of a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the health insurer's current utilization management processes.

(e) An insured or the insured's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing an internal appeal with the health insurer pursuant to Section 2719 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-19) and any subsequent rules or regulations issued thereunder.

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

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

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

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

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

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

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

(1) “Authorization” means approval by the health insurer to provide payment for the prescription drug.

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

(3) “Step therapy exception” means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual insured.

(4) “Utilization review organization” means an entity that conducts utilization review, other than a health insurer performing its own utilization review.

(j) Nonformulary prescription drugs shall include any drug for which an insured’s copayment or out-of-pocket costs are different

than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.

(k) This section does not affect an insured's or policyholder's eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).

(*l*) This section does not restrict or impair the application of any other provision of this part.

(m) This section and Section 10123.191 apply to both the health insurer and a utilization review organization that performs utilization review or utilization management functions on the insurer's behalf. Commencing January 1, 2022, a contract between a health insurer and a utilization review organization that performs utilization review or utilization management functions on the insurer's behalf shall include terms that require the utilization review organization to comply with this section and Section 10123.191.

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