Assembly Bill No. 347

CHAPTER 742

An act to amend Sections 1367.241 and 1367.244 of, and to add Section 1367.206 to, the Health and Safety Code, and to amend Sections 10123.191, 10123.197, and 10123.201 of the Insurance Code, relating to health care coverage.

[Approved by Governor October 9, 2021. Filed with Secretary of State October 9, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 347, Arambula. Health care coverage: step therapy.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene), 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 authorizes a health insurer to require step therapy if there is more than one drug that is appropriate for the treatment of a medical condition, and authorizes a health care service plan to utilize step therapy consistent with Knox-Keene. Under existing law, if a health care service plan, health insurer, or contracted physician group fails to respond to a completed prior authorization request from a prescribing provider within a specified timeframe, the prior authorization request is deemed to have been granted.

This bill would clarify that a health care service plan that provides coverage for prescription drugs may require step therapy, as defined, if there is more than one drug that is clinically appropriate for the treatment of a medical condition. The bill would require a health care service plan or health insurer to expeditiously grant a step therapy exception request if the health care provider submits justification and supporting clinical documentation, as specified, 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 or insured, based on specified criteria. The bill would authorize a health care provider or prescribing provider to 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 or health insurer's current utilization management processes. The bill would authorize an enrollee or insured, or their designee or guardian, to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request, as specified. The bill would require a prior authorization or step therapy exception request to be deemed approved for the duration of the prescription, including refills, if a health

care service plan, health insurer, or contracted physician group fails to send an approval or denial within a specified timeframe. Commencing January 1, 2022, the bill would require a contract between a health care service plan or health insurer and a utilization review organization that performs utilization review or utilization management functions on behalf of health care service plans or health insurers, or between a health care service plan and another contracted entity, to include terms that require the utilization review organization or other contracted entity to comply with specified provisions relating to step therapy determinations and procedures. 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.

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

SECTION 1. Section 1367.206 is added to the Health and Safety Code, 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 or interchangeable biological product 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 1367.241 of the Health and Safety Code is amended to read:

1367.241. (a) Notwithstanding any other law, on and after January 1, 2013, a health care service plan that provides coverage for prescription drugs shall accept only the prior authorization form developed pursuant to subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs. This section does not apply in the event that a physician or physician group has been delegated the financial risk for prescription drugs by a health care service plan and does not use a prior authorization process. This section does not apply to a health care service plan, or to its affiliated providers, if the health care service plan owns and operates its pharmacies and does not use a prior authorization process for prescription drugs.

(b) (1) (A) If a health care service plan, contracted physician group, or utilization review organization fails to notify a prescribing provider of its coverage determination within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization or step therapy exception request, the prior authorization or step therapy exception request shall be deemed approved for the duration of the prescription, including refills. The requirements of this subdivision shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code. Medi-Cal managed care health care service plans that contract under those chapters shall not be required to maintain an external exception request review as provided in Section 156.122 of Title 45 of the Code of Federal Regulations.

(B) The external exception request review process shall apply to a denial of a prior authorization or step therapy exception request. An independent review organization's reversal of a health care service plan's denial of a request for an exception, prior authorization, or a step therapy exception shall be binding on the health care service plan and shall apply for the duration of the prescription, including refills. A health care service plan shall notify the enrollee and prescribing provider of the independent review organization's coverage determination, or request for additional or clinically relevant material information necessary to make a coverage determination, within the time limits required by paragraph (2). This subparagraph shall not affect or limit an enrollee's eligibility for independent medical review under Section 1374.30 or to file an internal appeal with the health care service plan.

(2) If a request for prior authorization or a step therapy exception is incomplete or clinically relevant material information necessary to make a coverage determination is not included, the health care service plan, contracted physician group, or utilization review organization shall notify the prescribing provider within 72 hours of receipt, or within 24 hours of receipt if exigent circumstances exist, what additional or clinically relevant material information is needed to approve or deny the prior authorization or step therapy exception request, or to appeal the denial thereof. Once the requested information is received, the applicable time period to approve or

deny a prior authorization or step therapy exception request, or to appeal, shall begin to elapse. If a coverage determination or request for additional or clinically relevant material information by a health care service plan, contracted physician group, or utilization review organization is not received by the prescribing provider within the time allotted, the prior authorization or step therapy exception request, or appeal of a denial thereof, shall be deemed approved for the duration of the prescription, including refills. In the event of a denial, the health care service plan, contracted physician group, or utilization review organization shall inform the prescribing provider and enrollee of the external appeal process under subparagraph (B) of paragraph (1), which shall also apply to a denial of a prior authorization or step therapy exception request.

(3) A health care service plan, contracted physician group, utilization review organization, or external independent review organization shall approve a step therapy exception request, or internal or external appeal of a denial thereof, if any of the criteria in subdivision (b) of Section 1367.206 are satisfied.

(c) On or before January 1, 2017, the department and the Department of Insurance shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health care service plan shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health care service plan.

(3) The completed form may also be electronically submitted from the prescribing provider to the health care service plan.

(4) The department and the Department of Insurance shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Insurance, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for prescription drugs by a health care service plan.

(2) A contracted physician group uses its own internal prior authorization process rather than the health care service plan's prior authorization process for plan enrollees.

(3) A contracted physician group is delegated a utilization management function by the health care service plan concerning any prescription drug, regardless of the delegation of financial risk.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health plan's group or individual contract.

(h) For purposes of this section:

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

(2) "Exigent circumstances" exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

(3) "Completed prior authorization request" means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

(4) "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.

SEC. 3. Section 1367.244 of the Health and Safety Code is amended to read:

1367.244. (a) A request for an exception to a health care service plan's step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 1367.241, and shall be treated in the same manner, and shall be responded to by the health care service plan in the same manner, as a request for prior authorization for prescription drugs.

(b) The department and the Department of Insurance shall include a provision for step therapy exception requests in the uniform prior authorization form developed pursuant to subdivision (c) of Section 1367.241.

(c) "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.

SEC. 4. Section 10123.191 of the Insurance Code is amended to read:

10123.191. (a) Notwithstanding any other law, on and after January 1, 2013, a health insurer that provides coverage for prescription drugs shall utilize and accept only the prior authorization form developed pursuant to

subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs.

(b) (1) If a health insurer, contracted physician group, or utilization review organization fails to notify a prescribing provider of its coverage determination within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization or step therapy exception request, the prior authorization or step therapy exception request shall be deemed approved for the duration of the prescription, including refills.

(2) If a request for prior authorization or a step therapy exception is incomplete or clinically relevant material information necessary to make a coverage determination is not included, the insurer, contracted physician group, or utilization review organization shall notify the prescribing provider within 72 hours of receipt, or within 24 hours of receipt if exigent circumstances exist, what additional or clinically relevant material information is needed to approve or deny the prior authorization or step therapy exception request, or to appeal the denial thereof. Once the requested information is received, the applicable time period to approve or deny a prior authorization or step therapy exception request, or to appeal, shall begin to elapse. If a coverage determination or request for additional or clinically relevant material information by an insurer, contracted physician group, or utilization review organization is not received by the prescribing provider within the time allotted, the prior authorization or step therapy exception request, or appeal of a denial thereof, shall be deemed approved for the duration of the prescription, including refills. In the event of a denial, the insurer, contracted physician group, or utilization review organization shall inform the prescribing provider and insured of the external appeal process under subdivision (h) of this section, which shall also apply to a denial of a prior authorization or step therapy exception request.

(3) A health insurer, contracted physician group, utilization review organization, or external independent review organization shall approve a step therapy exception request, or internal or external appeal of a denial thereof, if any of the criteria in subdivision (c) of Section 10123.201 are satisfied.

(c) On or before January 1, 2017, the department and the Department of Managed Health Care shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health insurer shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health insurer.

(3) The completed form may also be electronically submitted from the prescribing provider to the health insurer.

(4) The department and the Department of Managed Health Care shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Managed Health Care, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for the pharmacy or medical drug benefit by a health insurer.

(2) A contracted physician group uses its own internal prior authorization process rather than the health insurer's prior authorization process for the health insurer's insureds.

(3) A contracted physician group is delegated a utilization management function by the health insurer concerning any prescription drug, regardless of the delegation of financial risk.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health insurer's group or individual policy.

(h) A health insurer shall maintain a process for an external exception request review that complies with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. The external appeal process for exception requests shall also apply to a denial of a prior authorization or step therapy exception request. An independent review organization's reversal of a health insurer's denial of a request for an exception, prior authorization, or a step therapy exception shall be binding on the insurer and shall apply for the duration of the prescription, including refills. An insurer shall notify the insured and prescribing provider of the independent review organization's coverage determination, or request for additional or clinically relevant material information necessary to make a coverage determination, within the time limits required by paragraph (2) of subdivision (b). This subdivision shall not affect or limit an insured's eligibility for independent medical review under Section 10169 or to file an internal appeal with the insurer.

(i) For an individual, small group, or large group health insurance policy, a health insurer that provides coverage for prescription drugs shall comply with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

(j) For purposes of this section:

(1) "Prescribing provider" shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.

(2) "Exigent circumstances" exist when an insured is suffering from a health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function or when an insured is undergoing a current course of treatment using a nonformulary drug.

(3) "Completed prior authorization request" means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

(4) "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.

SEC. 5. Section 10123.197 of the Insurance Code is amended to read:

10123.197. (a) A request for an exception to a health insurer's step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 10123.191, and shall be treated in the same manner, and shall be responded to by the health insurer in the same manner, as a request for prior authorization for prescription drugs.

(b) The department and the Department of Managed Health Care shall include a provision for step therapy exception requests in the uniform prior authorization form developed pursuant to subdivision (c) of Section 10123.191.

(c) "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.

SEC. 6. 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 or interchangeable biological product 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.

SEC. 7. 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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