AMENDED IN SENATE JUNE 24, 2015

AMENDED IN ASSEMBLY JUNE 1, 2015

AMENDED IN ASSEMBLY MAY 20, 2015

AMENDED IN ASSEMBLY MAY 4, 2015

AMENDED IN ASSEMBLY APRIL 7, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 339

Introduced by Assembly Member Gordon
(Coauthor: Assembly Member Atkins)

February 13, 2015

An act to *amend Sections 1367.24 and 1367.205 of, and to* add Section 1342.71 ~~to~~ *to,* the Health and Safety Code, and to *amend Section 10123.192 of, and to* add ~~Section~~ *Sections* 10123.193 ~~to~~ *and 10123.201 to,* the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 339, as amended, Gordon. Health care coverage: outpatient 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 requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other

specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would require a *nongrandfathered group* health care service plan contract or ~~a~~ health insurance policy that is offered, renewed, or amended on or after ~~January 1,~~ *July 1,* 2016, *and a nongrandfathered individual health care service plan contract or health insurance policy that is offered, renewed, or amended on or after January 1, 2017,* and that provides coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent. The bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed $1/24$ of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days. *The bill would require these cost sharing limitations for a plan contract or policy that is a high deductible health plan to apply only once an enrollee's or insured's deductible has been satisfied for the year.* The bill would make these cost-sharing limits applicable only to covered outpatient prescription drugs that constitute essential health benefits, as defined. The bill would require a plan contract or policy to cover single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are clinically equally or more effective, as specified. The bill would prohibit, except as specified, a plan contract or policy from placing prescription medications that treat a specific condition on the highest cost tiers of a drug formulary. The bill would require a plan contract or policy to use specified definitions for each tier of a drug formulary.

Existing law requires every health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug, and requires these plans to maintain specified information that is required to be made available to the Director of the Department of Managed Health Care upon request.

This bill would also impose these requirements on a health insurer that provides prescription drug benefits, as provided. The bill would require a plan or insurer to respond to authorization requests for

nonformulary prescription drugs within specified timeframes. The bill would authorize a plan or insurer to require step therapy, as defined, when more than one drug is appropriate for the treatment of a medical condition, subject to specified requirements. The bill would require a plan or insurer that requires step therapy to have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements. The bill, with regard to an enrollee or insured changing plans or policies, would prohibit a new plan or insurer from requiring the enrollee or insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. The bill, except as specified, would require a plan or insurer that provides essential health benefits to allow an enrollee or insured to access his or her prescription drug benefits at an in-network retail pharmacy, and would authorize a plan or insurer to charge an enrollee or insured a different cost sharing for obtaining a covered drug at a retail pharmacy, and would require that cost-sharing amount to count towards the plan's or insurer's annual out-of-pocket limitation, as specified.

This bill would require a plan or insurer to maintain a pharmacy and therapeutics committee that is responsible for developing, maintaining, and overseeing any drug formulary list, as provided. The bill would require the committee to, among other things, evaluate and analyze treatment protocols and procedures related to the plan's or insurer's drug formulary at least annually.

Existing law requires the Department of Managed Health Care and the Department of Insurance to jointly develop a standard formulary template by January 1, 2017, and requires plans and insurers to use that template to display formularies, as specified. Existing law requires the standard formulary template to include specified information.

This bill would require the standard formulary template to include additional specified information, including which medications are covered, including both generic and brand name.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, this 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 is added to the Health and Safety Code, to read:

1342.71. (a) A *nongrandfathered group* health care service plan contract that is offered, amended, or renewed on or after ~~January 1,~~ *July 1,* 2016, shall comply with this section. *A nongrandfathered individual 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. This section does not apply to Medi-Cal managed care contracts.

(b) (1) A health care service plan that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A health care service plan that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. *In proposing cost sharing, the health care service plan shall consider the impact of cost sharing on medication adherence as demonstrated in peer-reviewed literature.*

(d) Consistent with federal law and guidance, and notwithstanding Section 1342.7 and any regulations adopted pursuant to that section, a health care service plan that provides coverage for outpatient prescription drugs shall demonstrate that the formulary or formularies maintained by the health care service plan do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for enrollees with a particular condition.

(1) A health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health care service plan is able to demonstrate to the director, consistent with clinical guidelines and peer-reviewed scientific and medical literature, that the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen. A health care service plan contract shall cover an extended release prescription drug that is clinically equally or more effective than a nonextended release product unless the health care service plan is able to demonstrate to the director, consistent with clinical guidelines and peer-reviewed scientific and medical literature, that the nonextended release product is clinically equally or more effective than the extended release product.

(2) A health care service plan contract shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health care service plan can demonstrate that such placement does not reduce the generosity of the benefits for enrollees with a particular condition. If there is more than one treatment that is the standard of care for a specific condition, the health care service plan shall not place most or all prescription medications that treat that condition on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health care service plan shall demonstrate that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

(4) A health care service plan shall demonstrate to the director that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(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 shall not exceed one-twenty-fourth of the annual out-of-pocket limit applicable to individual coverage under Section 1367.006 for a supply of up to 30 days.

(2) 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, paragraph (1) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.

(f) (1) If a health care service plan contract maintains a drug formulary grouped into tiers, including a fourth tier or specialty 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 preferred generic drugs and preferred brand name drugs if the cost to the health care service plan for a preferred brand name drug is comparable to those for generic 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 ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health care service plan's ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the enrollee to have special training for self-administration or special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health care service plan's ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) This section does not require a health care service plan contract to include a fourth tier, but if a health care service plan contract includes a fourth tier, the health care service plan contract shall comply with this section.

(3) This section does not require the health care service plan's ~~pharmaceutical~~ *pharmacy* and therapeutics committee to consider the cost of the prescription drug to the health care service plan.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health care service plan, but is based on clinically indicated, reasonable medical management practices.

(h) 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.

~~(h)~~

(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.

SEC. 2. Section 1367.24 of the Health and Safety Code is amended to read:

1367.24. (a) *(1)* Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a description of its ~~process, including timelines,~~ *process* for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. *The plan shall provide that the enrollee, the enrollee's designee, or the enrollee's prescribing provider may seek an authorization for a nonformulary prescription drug.* ~~Each~~

(2) Each plan shall respond to an authorization request within 72 hours following receipt of the authorization request for a nonurgent authorization. If the plan grants the authorization request, the plan shall provide coverage of the nonformulary drug for the duration of the prescription, including refills.

(3) Each plan shall provide that an urgent authorization may be obtained within 24 hours if an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, or if an enrollee is

undergoing a current course of treatment using a nonformulary prescription drug. A plan that grants an exception based on these urgent circumstances shall provide coverage of the nonformulary prescription drug for the duration of that urgent condition.

(4) If a plan imposes step therapy, the plan shall provide an expeditious process to authorize an exception to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements of this chapter and federal law, and any regulations issued thereunder. The process to authorize an exception to step therapy shall be consistent with this section, including the timelines provided in this section.

(5) Each plan shall provide a written description of its most current ~~process, including timelines,~~ *process* to its prescribing providers. For purposes of this section, a 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.

(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02.

(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.

(d) (1) A plan shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the plan delegates responsibility for the formulary to any entity, the obligation of the plan to comply with this chapter 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 enrollees.

(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 plan'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 federal Food and Drug Administration-approved drugs and new uses for existing drugs.

(H) Ensure the plan'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 enrollees.

(I) Ensure the plan'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.

(e) (1) A health care service plan may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of this chapter.

(2) (A) When there is more than one drug that is appropriate for the treatment of a medical condition, a plan may require step therapy. A plan that requires step therapy shall comply with the requirements specified in paragraph (4) of subdivision (a).

(B) In circumstances where an enrollee is changing plans, the new plan shall not require the enrollee to repeat step therapy when that enrollee is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new plan from imposing a prior authorization requirement pursuant to this section for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee.

(3) A plan 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) A plan that provides essential health benefits shall allow an enrollee to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the federal Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A health care service plan that provides essential health benefits may charge an enrollee a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the plan's annual limitation on cost sharing consistent with Section 1367.006.

~~(d)~~

(f) The process described in subdivision (a) by which enrollees may obtain medically necessary nonformulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage

and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.

~~(e)~~

(g) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:

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

(2) Records developed by the pharmacy and therapeutic committee of the plan, 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 enrollees of the plan, that fully describe the reasoning behind formulary decisions.

(3) Any plan 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 plan to encourage formulary compliance or otherwise manage prescription drug benefits.

~~(f)~~

(h) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the performance of the plan 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 plan as part of its report issued pursuant to Section 1380.

~~(g)~~

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

~~(h)~~

(j) For purposes of this section, *the following definitions shall apply:* ~~"authorization"~~

(1) "Authorization" means approval by the health care service plan 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.

~~(i)~~

(k) (1) Nonformulary prescription drugs shall include any drug for which an enrollee'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 or in cases in which the drug has been excluded in the plan contract pursuant to Section 1342.7.

(2) If a nonformulary drug is authorized consistent with this section, the cost sharing shall be the same as for a formulary drug consistent with subdivision (e) of Section 1342.71.

~~(j)~~

(l) Nothing in this section shall 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 a health care service plan 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.

SEC. 3. Section 1367.205 of the Health and Safety Code is amended to read:

1367.205. (a) In addition to the list required to be provided under Section 1367.20, a health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the plan on the plan's Internet Web site in a manner that is accessible and searchable by potential enrollees, enrollees, ~~and providers.~~ *providers, the general public, the department, and federal agencies as required by federal law or regulations.*

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that

template to display the formulary or formularies for each product offered by the plan.

(b) (1) By January 1, 2017, the department and the Department of Insurance shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Insurance shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Insurance shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include the notification described in subdivision (c) of Section 1363.01, and as applied to a particular formulary for a product offered by a plan, shall do all of the following:

(A) Include information on ~~cost-sharing~~ *cost sharing* tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate enrollees about the differences between drugs administered or provided under a health care service plan's medical benefit and drugs prescribed under a health care service plan's prescription drug benefit and about how to obtain coverage information regarding drugs that are not covered under the plan's prescription drug benefit.

(D) Include information to educate enrollees that health care service plans that provide prescription drug benefits are required to have a method for enrollees to obtain prescription drugs not listed in the health plan drug formulary if the drugs are deemed medically necessary by a clinician pursuant to Section 1367.24.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the plan's drug formulary each medication is in.

(c) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a

health care service plan product and includes the drugs covered under the pharmacy benefit of the product.

SEC. 4. Section 10123.192 of the Insurance Code is amended to read:

10123.192. (a) A health insurer that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the insurer on the insurer's Internet Web site in a manner that is accessible and searchable by potential insureds, insureds, ~~and providers.~~ *providers, the general public, the department, and federal agencies as required by federal law or regulations.*

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the insurer.

(b) (1) By January 1, 2017, the department and the Department of Managed Health Care shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Managed Health Care shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Managed Health Care shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include a notification that the presence of a drug on the insurer's formulary does not guarantee that an insured will be prescribed that drug by his or her prescribing provider for a particular medical condition. As applied to a particular formulary for a product offered by an insurer, the standard formulary template shall do all of the following:

(A) Include information on ~~cost-sharing~~ *cost sharing* tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate insureds about the differences between drugs administered or provided under a health insurer's medical benefit and drugs prescribed under a health insurer's prescription drug benefit and about how to obtain coverage information about drugs that are not covered under the health insurer's prescription drug benefit.

(D) Include information to educate insureds that health insurers that provide prescription drug benefits are required to have a method for insureds to obtain prescription drugs not listed in the health insurer's drug formulary if the drugs are deemed to be medically necessary by a clinician pursuant to Section 1367.24 of the Health and Safety Code, as required by clause (iv) of subparagraph (A) of paragraph (2) of subdivision (a) of Section 10112.27.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the health insurer's drug formulary each medication is in.

(c) The commissioner may adopt regulations as may be necessary to carry out the purposes of this section. In adopting regulations, the commissioner shall comply with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health insurance product and includes the drugs covered under the pharmacy benefit of the product.

~~SEC. 2.~~

SEC. 5. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) A ~~policy of health insurance~~ *nongrandfathered group policy of health insurance* that is offered, amended, or renewed on or after ~~January 1,~~ *July 1,* 2016, shall comply with this section. *A nongrandfathered individual 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.

(b) (1) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. *In proposing cost sharing, the health insurer shall consider the impact of cost sharing on medication adherence as demonstrated in peer-reviewed literature.*

(d) Consistent with federal law and guidance, a policy of health insurance that provides coverage for outpatient prescription drugs shall demonstrate that the formulary or formularies maintained by the health insurer do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for insureds with a particular condition.

(1) A policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health insurer is able to demonstrate to the commissioner, consistent with clinical guidelines and peer-reviewed scientific and medical literature, that the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen. A policy of health insurance shall cover an extended release prescription drug that is clinically equally or more effective than a nonextended release product unless the health insurer is able to demonstrate to the commissioner, consistent with clinical guidelines and peer-reviewed scientific and medical literature, that the nonextended release product is clinically equally or more effective than the extended release product.

(2) A policy of health insurance shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health insurer can demonstrate that such placement does not reduce the generosity of the benefits for insureds with a particular condition. If there is more than one treatment that is the standard of care for a specific condition, the health insurer shall not place most or all prescription

medications that treat that condition on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health insurer shall demonstrate that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

(4) A health insurer shall demonstrate to the commissioner that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(e) *(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 shall not exceed one-twenty-fourth of the annual out-of-pocket limit applicable to individual coverage under Section 10112.28 for a supply of up to 30 days.

(2) 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, paragraph (1) of this subdivision shall apply only once an insured's deductible has been satisfied for the year.

(f) (1) If a policy of health insurance maintains a drug formulary grouped into tiers, including a fourth tier or specialty tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of preferred generic drugs and preferred brand name drugs if the cost to the health insurer for a preferred brand name drug is comparable to those for generic drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health insurer's ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the insured to have special training for self-administration or special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health insurer's ~~pharmaceutical~~ *pharmacy* and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) This section does not require a policy of health insurance to include a fourth tier, but if a policy of health insurance includes a fourth tier, the policy of health insurance shall comply with this section.

(3) This section does not require the health insurer's ~~pharmaceutical~~ *pharmacy* and therapeutics committee to consider the cost of the prescription drug to the health insurer.

(g) 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)~~

(h) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health insurer, but is based on clinically indicated, reasonable medical management practices.

SEC. 6. Section 10123.201 is added to the Insurance Code, to read:

10123.201. (a) (1) Every health insurer that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 2016, every insurer that provides prescription drug benefits shall file with the commissioner a description of its process for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the commissioner. The insurer shall provide that the insured, the insured's designee, or the insured's prescribing provider may seek an authorization for a nonformulary prescription drug.

(2) Each insurer shall respond to an authorization request within 72 hours following receipt of the authorization request for a nonurgent authorization. If the insurer grants the authorization request, the insurer shall provide coverage of the nonformulary drug for the duration of the prescription, including refills.

(3) Each insurer shall provide that an urgent authorization may be obtained within 24 hours if an insured is suffering from a health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function, or if an insured is undergoing a current course of treatment using a nonformulary prescription drug. An insurer that grants an exception based on these urgent circumstances shall provide coverage of the nonformulary prescription drug for the duration of that urgent condition.

(4) If an insurer imposes step therapy, the insurer shall provide an expeditious process to authorize an exception to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements of this part and federal law, and any regulations issued thereunder. The process to authorize an exception to step therapy shall be consistent with this section, including the timelines provided in this section.

(5) Each insurer shall provide a written description of its most current process to its prescribing providers. For purposes of this section, a 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.

(b) Any insurer that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the insured. The notice shall indicate that the insured may file a grievance with the insurer if the insured objects to the disapproval, including any alternative drug or treatment offered by the insurer. The notice shall comply with Section 10133.661.

(c) (1) 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 federal 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.

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

(2) (A) When there is more than one drug that is appropriate for the treatment of a medical condition, a health insurer may require step therapy. A health insurer that requires step therapy shall comply with the requirements specified in paragraph (4) of subdivision (a).

(B) In circumstances where an insured is changing policies, the new policy shall not require the insureds to repeat step therapy when that insured is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition. Nothing in this section shall preclude the new policy from imposing a prior authorization requirement pursuant to subdivision (a) for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former policy, or preclude the prescribing provider from prescribing another drug covered by the new policy that is medically appropriate for the insured.

(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) 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 federal Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. An insurer that provides essential health benefits 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.

(e) The process described in subdivision (a) by which insureds may obtain medically necessary nonformulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage and disclosure forms, as required by Section 10603, issued on or after January 1, 2016.

(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 therapeutic 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.

(j) (1) 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.

(2) If a nonformulary drug is authorized consistent with this section, the cost sharing shall be the same as for a formulary drug consistent with subdivision (e) of Section 10123.193.

(k) Nothing in this section shall be construed to restrict or impair the application of any other provision of this part.

~~SEC. 3.~~

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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