§ 1367.215. Coverage of pain management medications for terminally ill patients

(a) Every health care service plan contract that covers prescription drug benefits shall provide coverage for appropriately prescribed pain management medications for terminally ill patients when medically necessary. The plan shall approve or deny the request by the provider for authorization of coverage for an enrollee who has been determined to be terminally ill in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the plan's receipt of the information requested by the plan to make the decision. If the request is denied or if additional information is required, the plan shall contact the provider within one working day of the determination, with an explanation of the reason for the denial or the need for additional information. The requested treatment shall be deemed authorized as of the expiration of the applicable timeframe. The provider shall contact the plan within one business day of proceeding with the deemed authorized treatment, to do all of the following:

(1) Confirm that the timeframe has expired.

(2) Provide enrollee identification.

(3) Notify the plan of the provider or providers performing the treatment.

(4) Notify the plan of the facility or location where the treatment was rendered.

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

(c) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

HISTORY:
Added Stats 1998 ch 984 § 3 (AB 2305).
Amended Stats 2002 ch 791 § 2 (SB 842).

§ 1367.22. Plan's obligations relating to drug previously approved for enrollee's medical condition

(a) A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

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

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

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

HISTORY:
Added Stats 1998 ch 68 § 3 (AB 974).
Amended Stats 2002 ch 760 § 2 (AB 3048).

§ 1367.23. Plan provision requiring notification of group con- tractholders and subscribers of cancellation

(a) On and after January 1, 1994, every group health care service plan contract, which is issued, amended, or renewed, shall include a provision requiring the health care service plan to notify the group contractholders in writing of the cancellation of the plan contract and shall include in their contract with group contractholders a provision requiring the group contractholder to mail promptly to each subscriber a legible, true copy of any notice of cancellation of the plan contract which may be received from the plan and to provide promptly to the plan proof of that mailing and the date thereof.

(b) The notice of cancellation from the group contractholder to the subscriber required by subdivision (a) shall include information regarding the conversion rights of persons covered under the plan contract upon termination of the plan contract. This information shall be in clear and easily understandable language.

HISTORY:
Added Stats 1993 ch 1154 § 1 (AB 1834).

§ 1367.24. Process for authorization of medically necessary nonfor- mulary prescription drug; Required recordkeeping by plan; Review of plan's provision of prescription drug benefits

(a) 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, for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, 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. Any health plan that is required to maintain an external exception request review process pursuant to subdivision (k) shall indicate in the notice required under this subdivision that the enrollee may file a grievance seeking an external exception request review.

(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) 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 subdivisions (a) and (b)of Section 1363, issued on or after July 1, 1999.

(e) 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) 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) 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) For purposes of this section, "authorization" means approval by the health care service plan to provide payment for the prescription drug.

(i) 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.

(j) 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.

(k) For any individual, small group, or large health plan contracts, a health care service plan's process described in subdivision (a) shall comply with the request for exception and external exception request review processes described in subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts as described in subdivision (l).

(l) "Medi-Cal managed care health care service plan contract" means any entity that enters into a contract with the State Department of Health Care Services 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.

(m) Nothing in this section shall be construed to affect an enrollee's or subscriber's eligibility to submit a grievance to the department for review under Section 1368 or to apply to the department for an independent medical review under Section 1370.4, or Article 5.55 (commencing with Section 1374.30) of this chapter.

HISTORY:

Added Stats 1998 ch 69 § 2 (SB 625). Amended Stats 1999 ch 83 § 100 (SB 966), ch 525 § 101 (AB 78), operative July 1, 2000; Stats 2002 ch 791 § 3 (SB 842); Stats 2015 ch 654 § 1 (SB 282), effective January 1, 2016; Stats 2023 ch 42 § 16 (AB 118), effective July 10, 2023.

§ 1367.241. Prior authorization for prescription drugs; External ex- ception request review

(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.

HISTORY:

Added Stats 2011 ch 648 § 1 (SB 866), effective January 1, 2012. Amended Stats 2012 ch 162 § 81 (SB 1171), effective January 1, 2013;

Stats 2015 ch 654 § 2 (SB 282), effective January 1, 2016; Stats 2021 ch 742 § 2 (AB 347), effective January 1, 2022.

§ 1367.243. Prescription drug reporting requirements for health ser- vice plans reporting rate information; Legislative report on drug cost impact on health care premiums

(a)(1) A health care service plan that reports rate information pursuant to Section 1385.03 or 1385.045 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health care service plans.

(c) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2019, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 1385.045.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

HISTORY:

Added Stats 2017 ch 603 § 1 (SB 17), effective January 1, 2018.

§ 1367.244. Request for exception to plan's step therapy process for prescription drugs

(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.

HISTORY:

Added Stats 2015 ch 621 § 1 (AB 374), effective January 1, 2016. Amended Stats 2021 ch 742 § 3 (AB 347), effective January 1, 2022.