Date of Hearing: June 9, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
SB 964 (Smallwood-Cuevas) – As Amended May 14, 2026

SENATE VOTE: 39-0

SUBJECT: Prescription drug coverage: dose adjustments.

SUMMARY: Authorizes a treating provider to request, and requires they be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of an enrollee or insured without prior authorization (PA) or subsequent utilization management (UM), as specified. Specifically, **this bill**:

1) Authorizes a treating provider to request, and requires they be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of an enrollee or insured without PA or subsequent UM if all the following conditions are met:

    a) The drug previously had been approved for coverage by the plan for an enrollee or insured's chronic medical condition or cancer treatment and the treating provider continues to prescribe the drug for the chronic medical condition or cancer treatment;

    b) The drug is not an opioid or a scheduled controlled substance;

    c) The dose has not been adjusted more than two times without PA; and,

    d) If the adjusted dose or frequency is for an off-label use, two articles from major peer-reviewed medical journals have presented data supporting the proposed off-label use as generally safe and effective as described in existing law.

EXISTING LAW:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 and the California Department of Insurance (CDI) to regulate health insurers. [Health and Safety Code (HSC) § 1340, *et seq*., and Insurance Code (INS) § 106, *et seq.*]

2) Establishes as California's essential health benefits (EHBs) benchmark, the Kaiser Small Group Health Maintenance Organization contract, existing California mandates, and 10 federal Patient Protection and Affordable Care Act mandated benefits, including prescription drugs. [HSC § 1367.005 and INS § 10112.27]

3) Prohibits a health plan contract or insurance policy that covers prescription drug benefits from limiting or excluding coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

    a) The drug is approved by the FDA;

b) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or the drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. Requires, if the drug is not on the plan formulary, the participating subscriber's request to be considered pursuant to an expeditious process;

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

i) The American Hospital Formulary Service's Drug Information;

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

(1) The Elsevier Gold Standard's Clinical Pharmacology;

(2) The National Comprehensive Cancer Network Drug and Biologics Compendium; or,

(3) The Thomson Micromedex DrugDex; and,

iii) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal. [HSC § 1367.21 and INS § 10123.195]

4) Requires any coverage required pursuant to 2) above to also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract. States that 2) above shall not be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA. [HSC § 1367.21 and INS § 10123.195]

5) Defines "chronic and seriously debilitating" as diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity. [HSC § 1367.21 and INS § 10123.195]

6) Prohibits a health plan, on or after July 1, 1999, from limiting or excluding 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. Exempts drugs that are prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA. [HSC § 1367.22]

7) Requires every health 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. Requires, on or before July 1, 1999, every health plan that provides prescription drug benefits to file with DMHC a description of its process, including

timelines, for responding to authorization requests for nonformulary drugs. Requires any changes to this process to be filed with DMHC. Requires each plan to provide a written description of its most current process, including timelines, to its prescribing providers. [HSC § 1367.24]

FISCAL EFFECT: According to the Senate Appropriations Committee, unknown ongoing costs, likely low millions for DMHC (Managed Care Fund). Unknown one-time costs, likely minor, for CDI for state administration (Insurance Fund).

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, more than 16 million Californians live with at least one chronic condition, and many depend on prescription medications to manage their health and, in some cases, to survive. The author states that for these patients, adjustments in dosage or frequency are often a routine and medically necessary part of effective treatment — not a new or different therapy. The author continues that under current insurance practices, even minor, clinically appropriate adjustments are frequently treated as entirely new treatments. The author notes that this triggers burdensome prior authorization requirements, denials, and lengthy appeals processes that delay care, disrupt treatment plans, and place unnecessary administrative strain on patients and providers. The author argues that these delays can lead to worsened health outcomes due to preventable complications or disease progression. The author states that this bill addresses that gap by ensuring that patients with chronic, complex conditions — such as Crohn's disease — may receive up to two clinically justified dose or frequency adjustments per covered medication without repeated prior authorization barriers. The author concludes that by protecting continuity of care while maintaining appropriate clinical safeguards, the measure supports better health outcomes, reduces avoidable delays, and promotes a more efficient and patient-centered healthcare system.

2) **BACKGROUND**.

   a) **UM and Utilization Review (UR).** UM and UR are processes used by health plans to evaluate and manage the use of health care services. UR can occur prospectively, retrospectively, or concurrently and a plan can approve, modify, delay or deny in whole or in part a request based on its medical necessity. PA is a UR technique used by health plans that requires patients to obtain approval of a service or medication before care is provided. PA is intended to allow plans to evaluate whether care that has been prescribed is medically necessary for purposes of coverage. PA is one type of UM tool that's used by health plans, along with others such as concurrent review and step therapy, to control costs, limit unnecessary care, and evaluate safety and appropriateness of a service.

      i) **Overall impact of PA**. In 2023, the California Health Benefit Review Program (CHBRP) published a report to help the Legislature better understand the ways in which PA is used in California. CHBRP noted that PA is an imperfect instrument that is utilized in a myriad of ways. This poses a challenge for policymakers, payers, patients, and providers since PA is generally intended to decrease costs, but it may also contribute to delays in treatment and additional barriers to care. Currently, evidence is limited as to the extent to which health insurance uses PA and its impact on the performance of the health care system, patient access to appropriate care, and the health and financial interests of the general public. Despite the limited evidence,

there is clear frustration from both patients and providers regarding PA practices. According to CHBRP, complaints range from the time required to complete the initial authorization request and pursue denials, to delays in care, to a general lack of transparency regarding the process and criteria used to evaluate PA requests. CHBRP further notes that people with disabilities, younger patients, African Americans, and people with lower incomes are more likely to report administrative burdens, including delays in care, due to PA.

b) **Prescription drug coverage**. According to CHBRP, almost all enrollees in plans and policies regulated by DMHC and CDI have pharmacy benefit coverage. Pharmacy benefits cover outpatient prescription drugs by covering prescriptions that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy. Plans and policies that include a pharmacy benefit may apply UM techniques, including prior authorization, step therapy, and formulary requirements. UM techniques are generally applied to new prescriptions, but they may also be applied if there is a change in dose or dosage form (inhaled vs. oral, immediate vs. extended release, etc.) for a recurring prescription. Additionally, they may be applied to recurring prescriptions, should the enrollee's plan or policy alter applicable UM techniques or if an enrollee switches from one plan or policy to another. Prescribers submit medical documentation along with a prior authorization request for an enrollee seeking to fill a prescription for a drug when UM requirements are present. Plans and insurers regulated by DMHC and CDI must complete UR for a completed prior authorization request within 72 hours (within 24 hours in emergency circumstances) or coverage for the script is required. UR may result in the plan or insurer covering the drug or denying coverage. Should a plan or insurer review a prior authorization request and then deny coverage, an enrollee, with assistance from the prescriber, may appeal the decision to the plan or insurer. Plans and insurers regulated by DMHC and CDI generally must review and respond to completed appeals within 30 days. The plan or insurer may agree to the appeal and cover the drug or may uphold their original denial. Should a plan or insurer review an appeal and uphold their denial, an enrollee, with assistance from the prescriber, may appeal the second denial to the appropriate regulator for state regulated health insurance. The regulator may uphold the denial or may require the plan or insurer to cover the drug.

c) **Continuity Provisions of California Law.** California law with respect to continuity of coverage requires that plans regulated by DMHC or CDI that include a pharmacy benefit not limit or exclude coverage for a drug for an enrollee when: i) the drug previously had been approved for coverage by the plan for a medical condition of the enrollee; ii) the plan's prescribing provider continues to prescribe the drug for the medical condition; and, iii) provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. This bill amends existing law to allow a prescriber to adjust the dose or frequency of a drug previously approved for a chronic medical condition or cancer. This authorization does not apply to opioids or a scheduled controlled substance.

3) **SUPPORT**. The Crohn's & Colitis Foundation, sponsor of this bill, states that many chronic diseases are well-managed with the regular use of the right medication at the right dose. The sponsor continues that when providers work with patients to find an effective medication, over time they may require adjustment of the amount given, either by increasing the dose or decreasing the dosing interval to achieve an effective therapeutic response. The sponsor notes

that every single dose adjustment requires approval by the health plan, which, unfortunately, are often routinely denied requiring an appeal, particularly if the necessary dose is different than what's on the label. The sponsor argues that most prescriptions for dose adjustment that are initially denied are ultimately approved when appealed. The sponsor cites that in 2021, 87.5% of inflammatory bowel disease (IBD) patients who appealed their insurance medication denials through DMHC's Independent Medical Review process eventually had their request approved. The sponsor notes this means that patients were denied an effective dose of a life preserving medication for an unnecessary period. The sponsor continues that IBD is just one of many chronic illnesses for which an inadequate dose can cause serious or life threating complications. The sponsor argues that if insurance companies are allowed to continue to deny prescribed changes in dosage levels, chronically ill patients will be unable to receive the critical treatment they need. The sponsor concludes that this bill addresses this problem by ensuring patients have appropriate access to the right dose of a life-sustaining drug that meets their specific medical needs as determined by their physician.

4) **OPPOSED UNLESS AMENDED**. The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) oppose this bill unless it is amended. CAHP and ACLHIC state that this bill may create potential patient safety concerns for their enrollees given that it specifically excludes language that requires that a drug must be prescribed consistent with FDA-labeled dosages or prescribed for something that is consistent with the use for which the drug has been approved for marketing by the FDA. CAHP and ACLHIC continue that limiting a health plan or insurer's oversight may cause potentially adverse reactions to enrollees if a dosage change is not done correctly. Furthermore, CAHP and ACLHIC believe that this bill will add costs to our healthcare delivery system by encouraging the use of expensive specialty and brand name drugs when a generic or lower cost brand equivalent is available and clinically appropriate, thereby impacting affordability of health care coverage in the state. Lastly, CAHP and ACLHIC argue that this bill would undermine existing UM protocols for prescription drugs by nullifying these processes and allowing a provider to increase the dosage of a drug up to two times without giving a health plan or insurer the ability to ensure clinically appropriate use. CAHP and ACLHIC appreciate recent amendments requiring two articles from major peer-reviewed medical journals supporting proposed off-label use as safe and effective, however it does not fully address concerns raised around patient safety. CAHP and ACLHIC request amendments to require the dose and frequency of the drugs prescribed under this bill to conform to FDA-approved labeling and applicable FDA guidance.

5) **PREVIOUS LEGISLATION**.

   a) SB 306 (Becker), Chapter 408, Statutes of 2025, excludes, from health plan and insurer PA requirements, specified covered health care services that have been approved by the plan or insurer 90% or more times as determined by DMHC and CDI after health plan and insurer reporting and evaluation by DMHC and CDI. SB 306 sunsets on January 1, 2034.

   b) AB 2169 (Bauer-Kahan) of 2024 was substantially similar to this bill. AB 2169 was held on the Senate Appropriations Committee suspense file.

   c) SB 70 (Wiener) of 2023 would have prohibited health plans and insurers from limiting or excluding coverage for a drug, dose of a drug, or dosage form of a drug on the basis that

a drug, dose of a drug, or dosage form of a drug is different from the use approved for marketing by the FDA if specified conditions are met, including that the drug has been previously covered for a chronic condition or cancer. SB 70 also would have prohibited plans/insurers from limiting or excluding coverage, or requiring additional cost-sharing for a drug, dosage, or dosage form of a drug that was previously approved. SB 70 was held on the Assembly Appropriations Committee suspense file.

d) SB 853 (Wiener) of 2022 would have prohibited a health plan or insurer that provides coverage for prescription drugs from limiting or declining to cover a drug or dose of a drug as prescribed or imposing additional cost-sharing for covering a drug as prescribed, if specified criteria apply. SB 853 would have provided that a reduction or termination of an ongoing and approved course of treatment before the end of the treatment or the end or amendment of the policy is an adverse benefit determination, and required a health plan or insurer to notify an enrollee or insured, or their representative, and the enrollee's or insured's provider in writing, as specified. SB 853 also would have required a plan or insurer that has approved an ongoing course of treatment to provide continuing coverage pending appeal or review. Finally, SB 853 would have prohibited a health plan or insurer from limiting or declining to cover a drug or dose of a drug as prescribed, or impose additional cost-sharing for covering a drug as prescribed, if specified provisions apply, including that the drug was previously covered by the plan or insurer or the enrollees or insured's prior private or public health care coverage for the enrollees or insurer's medical condition. SB 853 was held on the Assembly Appropriations Committee suspense file.

6) **POLICY COMMENT.** Amendments taken in the Senate allow dose adjustment and frequency changes that differ from FDA-approved label usage if there are two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use as generally safe and effective. While this language cross-references and mirrors a similar process in existing law, it does not include the current statute's exemption if "there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal." The author and sponsors may wish to consider if such an exemption should be explicitly permitted in this bill.

REGISTERED SUPPORT / OPPOSITION:

Support

Crohn's and Colitis Foundation (sponsor)
California Chapter American College of Cardiology
California Chronic Care Coalition
California Hospital Association
California Medical Association
California Pharmacists Association
California Retired Teachers Association
California Rheumatology Alliance
Health Access California
St. John's Community Health
Western Center on Law & Poverty

Opposition

None on file

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