Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2169 (Bauer-Kahan) – As Amended March 21, 2024

SUBJECT: Prescription drug coverage: dose adjustments.

SUMMARY: Authorizes a licensed health care professional to request, and to be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of the enrollee or insured without prior authorization or subsequent utilization management under specified conditions. Specifically, **this bill**:

1) Authorizes a licensed health care professional to request, and to be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of the enrollee or insured without prior authorization or subsequent utilization management if 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 plan or insurer's prescribing provider continues to prescribe the drug for the enrollee's chronic medical condition or cancer treatment;

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

    c) The dose has not been adjusted more than two times without prior authorization.

2) Prohibits the health plan or insurer from limiting or excluding coverage of that prescription if the enrollee or insured has been continuously using a prescription drug selected by the enrollee or insured's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage.

3) Exempts Medi-Cal managed care plans contracting with the Department of Health Care Services from the provisions of this bill.

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 California Department of Insurance (CDI) to regulate health insurance. [Health and Safety Code (HSC) §1340, *et seq*., 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) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review (UR) or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:

a) Be developed with involvement from actively practicing health care providers;
b) Be consistent with sound clinical principles and processes;
c) Be evaluated, and updated if necessary, at least annually;
d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

4) Requires reviews, for purposes of Independent Medical Review (IMR), to determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee or insured and any of the following:
   a) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;
   b) Nationally recognized professional standards;
   c) Expert opinion;
   d) Generally accepted standards of medical practice; or,
   e) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious. [HSC §1374.33 and INS §10169.3]

5) Requires, if a health plan or health insurer that provides coverage for prescription drugs or a contracted physicians group fails to respond to a prior authorization, or step therapy exception request, as specified, within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon the receipt of a completed request form, the request to be deemed granted. [HSC §1367.241 and INS §10123.191]

6) Authorizes a health plan or insurer that provides coverage for prescription drugs to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition. [HSC §1367.206 and INS §10123.201]

7) Prohibits a health plan contract 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 condition. Does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution, as authorized. Specifies that provisions do 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. [HSC §1367.22]

FISCAL EFFECT: Unknown. This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, nearly half of all Americans live with a chronic medical condition, and that number is expected to rise by 25% in the next 20 years. According to the California Health Care Foundation, 38% of Californians are living with one or more chronic medical conditions. Many Californians who suffer from chronic disease or illness rely on prescription medications to survive. One example is inflammatory bowel disease (IBD), a lifelong chronic illness that requires access to specific treatment as there is

no "one size fits all" treatment for everyone with IBD. When providers find an effective medication, over time adjustment is often necessary, either by increasing the dose or by decreasing the dosing interval. The author states that a change in dosage is not a different treatment, but insurance policies treat them as such. This creates long pre-approval, denial, and appeal processes that make treatment less effective and more expensive over the long term. The author concludes that this bill authorizes prescribers to adjust, up to two times, the dose or frequency of a drug without prior authorization or subsequent UM, as long as the drug has been approved for coverage by the plan and the plan's prescribing provider continues to prescribe it.

2) BACKGROUND.

a) Prescription drug coverage. According to the California Health Benefit Review Program, 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 (scripts) 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 script 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.

b) 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 and Colitis Foundation (CCF), sponsor of this bill, writes that most prescriptions for a dose adjustment that are initially denied are ultimately approved when appealed. For example, in 2021, 87.5% of IBD patients who appealed their insurance medication denials through the DMHC IMR process eventually had their request approved. This means that patients were denied an effective dose of a life preserving medication for an unnecessary period of time. Moreover, many patients do not know this appeal is available to them, and the process can be lengthy, leaving patients without their necessary medication until a final decision is made. According to CCF, when a decision is made, the patient's condition may have deteriorated or they were forced to move to another drug, which then limits future options and may not have the same therapeutic response as the previous drug at the right dose. Limiting access to medically necessary drugs and drug dosage is not adequate and does not represent quality care. CCF 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) **OPPOSITION.** The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP), contend that this bill would undermine existing utilization management 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, ACLHIC, AHIP note that clinical research and efficacy are not static and evolve over time. Oftentimes, a health plan may switch an enrollee to a more effective medication or a lower cost brand equivalent to treat a certain condition that is clinically appropriate and already on the health plan or insurer's formulary. This bill ignores these considerations and gives providers a free pass to increase the dose of a particular drug without having to provide the health plan with a reason why the enrollee/insured should remain on the drug at elevated doses. The opposition concludes this bill will increase health care costs in California and will add costs to our healthcare delivery system by encouraging the use of expensive specialty and brand name drugs.

5) **RELATED LEGISLATION.** SB 516 (Skinner) prohibits a health plan or health insurer from requiring a contracted health professional to complete or obtain a prior authorization for any covered health care services if the plan or insurer approved or would have approved not less than 90% of the prior authorization requests they submitted in the most recent completed one-year contracted period. SB 516 is pending in Assembly Appropriations Committee.

6) **PREVIOUS LEGISLATION.**

   a) SB 70 (Wiener) of 2023 was similar to this bill and would have additionally prohibit limiting or excluding coverage of a drug, dose of a drug, or dosage form of a drug that is prescribed for off-label use if the drug has been previously covered for a chronic condition or cancer, as specified, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary. Would have prohibited a health plan contract or health insurance policy from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. SB 70 was held in the Assembly Appropriations Committee.

b) SB 598 (Skinner) of 2023 was substantially similar to SB 516 (Skinner) and was held in Assembly Appropriations Committee.

c) SB 853 (Wiener) of 2022 was similar to SB 70 (Wiener) of 2023. SB 853 was held in the Assembly Appropriations Committee.

d) AB 347 (Arambula), Chapter 742, Statutes of 2021, requires a health plan or health insurer to expeditiously grant a step therapy exception if specified criteria are met, including that the health care provider submit necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, as specified.

REGISTERED SUPPORT / OPPOSITION:

Support

Crohn's & Colitis Foundation (sponsor)
California Chapter American College of Cardiology
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Retired Teachers Association
Children's Specialty Care Coalition
National Multiple Sclerosis Society, MS-CAN
Oncology Nursing Society

Opposition

America's Health Insurance Plans
Association of California Life & Health Insurance Companies
California Association of Health Plans

Analysis Prepared by: Kristene Mapile / HEALTH / (916) 319-2097