SENATE COMMITTEE ON HEALTH
Senator Richard Roth, Chair

BILL NO: AB 2169
AUTHOR: Bauer-Kahan
VERSION: March 21, 2024
HEARING DATE: June 26, 2024
CONSULTANT: Teri Boughton

SUBJECT: Prescription drug coverage: dose adjustments.

SUMMARY: Authorizes a licensed health care professional to adjust the dose or frequency of a drug to meet the specific medical needs of an enrollee or insured without prior authorization or subsequent utilization management, no more than two times, if the drug has previously been approved for coverage by the plan or insurer and the prescribing provider continues to prescribe the drug. Prohibits a health plan or insurer from limiting or excluding coverage if the enrollee or insured has been continuously using a prescription drug selected by the prescribing provider for the medical condition while covered by their current or previous health coverage.

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 (Knox-Keene Act); California Department of Insurance (CDI) to regulate health and other insurance; and, the Department of Health Care Services (DHCS) to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., and WIC §14000, et seq.]

2) 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 an enrollee's medical condition 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. This does not: preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution; apply to off-label use of drugs; or, prohibit a health plan/insurer from charging a copayment or a deductible or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits. [HSC §1367.22]

3) Requires health plans to maintain an expeditious process by which the prescribing provider may obtain authorization for a medically necessary nonformulary prescription drug. [HSC §1367.24]

4) Requires health plans to establish and maintain a system approved by DMHC under which enrollees may submit grievances to the plan. Requires a plan's response to also comply with federal requirements. [HSC §1368]

5) Establishes an Independent Medical Review (IMR) process, under which enrollee and insured grievances involving a disputed health care service are eligible for review. Defines "disputed health care service" as any health care service eligible for coverage and payment under the contract that has been denied, modified, or delayed by a decision of the plan/insurer, or contracting provider, in whole or in part due to a finding that the service is not medically necessary. [HSC §1374.30 and INS §10169]

6) Establishes a process for expeditiously reviewing IMR requests related to imminent and serious threat to the enrollee. [HSC §1374.31 and INS §10169.1]

7) Requires, if a health plan or insurer that provides coverage for prescription drugs or a contracted physicians group fails to respond to a prior authorization or step therapy exception request, 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]

8) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the time limits described in 7) above if the provider submits the necessary justification and clinical detail, as specified, when the enrollee or insured is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid. [HSC §1367.206(b)(5) and INS §10123.201(c)(2)(B)(v)]

This bill:

1) Authorizes a licensed health care professional to request, and requires the request to be granted, to adjust the dose or frequency of a drug to meet specific medical needs of an 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/insurer for an enrollee's or insured's chronic medical condition or cancer treatment and the prescribing 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; and,
    c) The dose has not been adjusted more than two times without prior authorization.

2) Prohibits a health plan or insurer from limiting or excluding coverage if the enrollee or insured has been continuously using the prescription drug selected by the 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 DHCS, as specified.

FISCAL EFFECT: According to the Assembly Appropriations Committee:

- DMHC estimates its cost for this bill to be approximately $24,000 in fiscal year (FY) 2024-25, $1.5 million in FY 2025-26, and $2.1 million in FY 2026-27 and annually thereafter (Managed Care Fund). DMHC states it anticipates additional workload to conduct independent medical reviews, revise survey methodology and develop tools to monitor compliance, review health plan filings of utilization management processes, and provide guidance to health plans. Additional costs include clinical and statistical consultants and software licensing. DMHC assumes the Office of Enforcement would need to address eleven referrals annually as a result of this bill. DMHC notes that generally, and depending on final enrollment data, a $1 million dollar increase to the Managed Care Fund could result in a 2-cent per month increase per enrollee on assessments to full-service health plans and a 1-cent increase per enrollee to specialized health plans. To the extent this bill and others

result in an additional assessment on health plans, consumers could face increased premiums.

- CDI estimates costs of $70,000 in FY 2024-25 and $80,000 in FY 2025-26 if the bill is implemented after CDI completes development of regulations related to prescription drug utilization management (Insurance Fund).
- Annual costs in the low hundreds of thousands of dollars to CalPERS (Public Employees Health Care Fund, special funds). For a broader bill, SB 70 (Wiener), of the current legislative session, the CHBRP estimated expenditures for CalPERS premiums would increase by $310,000. The state pays for approximately 60% of CalPERS enrollees. CalPERS costs for this bill would likely be lower than cost for SB 70.

PRIOR VOTES:

Assembly Floor:	65 - 1
Assembly Appropriations Committee:	12 - 1
Assembly Health Committee:	14 - 0

COMMENTS:

1) *Author's statement.* According to the author, according to the California Healthcare 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. 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. This bill authorizes prescribers to adjust, up to two times, the dose or frequency of a drug without prior authorization or subsequent utilization management, as long as the drug has been approved for coverage by the plan and the prescribing provider continues to prescribe it.

2) *California Health Benefits Review Program (CHBRP).* According to CHBRP, IBD includes Crohn's disease and ulcerative colitis; cystic fibrosis; eosinophilic enteritis; enteropathy; chronic pancreatitis; and, intestinal malabsorption. Regarding prescription drugs, CHBRP indicates that 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 utilization management techniques, including prior authorization, step therapy, and formulary requirements. Utilization management generally applies 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 utilization management 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 utilization management is required.

3) *DMHC Outpatient Prescription Drug Regulations.* Among other provisions, Title 28 of the California Code of Regulations, §1300.67.24 (d)(2) indicates that in circumstances where an

enrollee is changing plans, the new plan may 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. This does not preclude the new plan from imposing a prior authorization requirement 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. 1300.67.24 (d)(3) requires a plan to 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) *Prior legislation.* 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 drug, dose of a drug, or dosage form is different from the use approved for marketing by the Federal Food and Drug Administration (FDA) if specified conditions are met, including that the drug has been previously covered for a chronic condition or cancer. SB 70 would also 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 Suspense file.*

   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 requires 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 would also 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 that provides coverage for prescription drugs 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 in the Assembly Appropriations Committee.*

   AB 347 (Arambula, Chapter 742, Statutes of 2021) requires a health plan or 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. SB 347 authorizes an enrollee or insured or their designee, guardian, health care provider or prescribing provider to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request or step therapy exception request by filing a grievance, as specified. AB 347 deems a prior authorization request or step therapy exception request approved for the duration of the prescription, including refills, if a health plan, health insurer, or contracted physician group, or utilization review organization fails to notify a prescribing provider of its coverage determination within a specified timeframe. AB 347 additionally defines step therapy exception as 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.

AB 374 (Nazarian, Chapter 621, Statutes of 2015) authorizes a request for an exception to a payer's step therapy process for prescription drugs to be submitted in the same manner as request for prior authorization for prescription drugs. In addition, it requires the payer to treat, and respond to, the request in the same manner as a request for prior authorization for prescription drugs. AB 374 also requires DMHC and CDI to include a provision for step therapy exception requests in the uniform prior authorization form.

4) *Support.* According to this bill's sponsor, the Crohn's and Colitis Foundation, many Californians who suffer from chronic disease or illness rely on prescription medications to survive. One example is IBD, a lifelong chronic illness that requires access to specific treatment and when patients' needs are met, healthcare providers typically seek to avoid switching the medication of stable IBD patients, as finding a new treatment can be painful and time intensive. When insurance companies deny coverage of a medication or the optimization of dosage to an existing approved prescription, despite healthcare providers deeming medication vital to the patient's health, patients risk hospitalization and even death. Many chronic diseases are well-managed with the regular use of the right medication at the right dose. 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. Every single adjustment in dose requires approval by the health plan, which, unfortunately, are often routinely denied requiring an appeal. Even more frustrating is 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 DMHC's 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. In addition, 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. IBD is just one of many chronic illnesses for which an inadequate dose can cause serious or life threating complications. 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. Limiting access to medically necessary drugs and drug dosage is not adequate and does not represent quality care.

5) *Opposition.* Americas Health Insurance Plan, the Association of California Life and Health Insurance Companies, and the California Association of Health plans (plans) write 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. The plans are concerned that stripping health plans and insurers of the ability to review a dosage increase could have a deleterious effect on our enrollees/insureds. It is important to 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 plans are also concerned that this bill may create potential patient safety concerns for enrollees. When health plans and insurers choose to limit a drug or specific dose of a drug, it is generally for safety reasons. Specific reasons include potential abuse or overuse, inconsistent usage with FDA-approved labeling or to prevent use at doses that have not been studied or shown to be efficacious. They are also concerned that this bill 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. Limiting a health plan or insurer's oversight may cause potentially adverse reactions to our enrollees if a dosage change is not done correctly.

SUPPORT AND OPPOSITION:

Support: Crohn's and Colitis Foundation (sponsor)
California Academy of Family Physicians
California Chapter American College of Cardiology
California Chiropractic Association
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Retired Teachers Association
California Society of Health System Pharmacists
Children's Specialty Care Coalition
Everylife Foundation for Rare Diseases
Health Access California
National Multiple Sclerosis Society, MS-CAN

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

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