ASSEMBLY THIRD READING
AB 2169 (Bauer-Kahan)
As Amended March 21, 2024
Majority vote

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's chronic medical condition or cancer treatment without prior authorization or subsequent utilization management under specified conditions. Exempts Medi-Cal managed care plan contracts.

COMMENTS

1) *Prescription drug coverage.* According to the California Health Benefit Review Program (CHBRP), almost all enrollees in plans and policies regulated by the Department of Managed Health Care (DMHC) and California Department of Insurance (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 utilization management (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 utilization review (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.

2) *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.

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.

Arguments in 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.

Arguments in 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 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, 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.

FISCAL COMMENTS

According to the Assembly Appropriations Committee,

1) 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.

2) 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).

3) 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.

VOTES

ASM HEALTH: 14-0-2
YES: Bonta, Waldron, Aguiar-Curry, Arambula, Wendy Carrillo, Haney, Jones-Sawyer, Maienschein, McCarty, Joe Patterson, Rodriguez, Santiago, Schiavo, Weber
ABS, ABST OR NV: Flora, Sanchez

ASM APPROPRIATIONS: 12-1-2
YES: Wicks, Sanchez, Arambula, Bryan, Calderon, Wendy Carrillo, Mike Fong, Grayson, Haney, Hart, Pellerin, Villapudua
NO: Dixon
ABS, ABST OR NV: Jim Patterson, Ta

UPDATED

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