Office of Senate Floor Analyses
(916) 651-1520 Fax: (916) 327-4478

THIRD READING

Bill No: SB 70
Author: Wiener (D)
Amended: 4/18/23
Vote: 21

SENATE HEALTH COMMITTEE: 10-1, 4/12/23
AYES: Eggman, Glazer, Gonzalez, Hurtado, Limón, Menjivar, Roth, Rubio, Wahab, Wiener
NOES: Nguyen
NO VOTE RECORDED: Grove

SENATE APPROPRIATIONS COMMITTEE: 5-2, 5/18/23
AYES: Portantino, Ashby, Bradford, Wahab, Wiener
NOES: Jones, Seyarto

SUBJECT: Prescription drug coverage

SOURCE: Crohn's & Colitis Foundation

DIGEST: This bill (1) prohibits 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 if specified conditions are met, including that the drug has been previously covered for a chronic condition or cancer; (2) prohibits plans and 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, as specified; and (3) clarifies cost-sharing changes are permitted at contract renewal, and if a dosage or dosage form change results in coverage at a higher tier.

ANALYSIS:

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) and the California Department of Insurance (CDI) to regulate health and other insurers. [HSC §1340, et seq., and INS §106, et seq.]

2) 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 specified conditions have been met. This is referred to as "Off-label use."[HSC §1367.21 and INS §10123.195] 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. [HSC §1367.21 and INS §10123.195] Requires pursuant to regulations a plan to provide coverage for the medically necessary dosage and quantity of the drug prescribed for treatment consistent with professionally recognized standards of practice. [Title 28 CCR §1300.67.34]

3) 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. This is referred to as the "continuity of care" law. This does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution. This does not apply to Off-label use of drugs. This does not prohibit a health 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. [HSC §1367.22]

4) 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]

5) Establishes an 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, 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]

This bill:

Health Plan Provisions

1) Adds "dose of a drug, and dosage form" and excludes the requirement that the drug be on the plan formulary, as specified, to the "Off-label use" prohibition. Requires that the drug has been previously covered for a chronic condition or cancer.

2) Prohibits a health plan contract the covers prescription drug benefits from requiring additional cost-sharing not already imposed, for a drug, dosage of a drug, or dosage form 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, dosage of a drug, or dosage form is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

3) Allows the drug continuity of care law and the provision described in 2) of "this bill" directly above to apply to Off-label use of drugs.

Insurer Provisions

4) Applies the provisions described in 1) of "this bill" above to an individual or group health insurance policy issued, delivered, or renewed in this state, or a certificate of group insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state, that directly or indirectly covers prescription drugs.

5) Requires the health insurer to determine whether or not this bill applies to a prior authorization or exception from step therapy request for coverage of a prescription, and to request any additional or omitted information that is needed to make a coverage determination, as specified.

6) Prohibits a health insurance policy that covers prescription drugs that is issued, amended, or renewed on or after January 1, 2024, from limiting or excluding coverage, or requiring authorization or additional cost-sharing that is not generally applicable to drugs covered by the policy, for a drug, dosage of a drug, or dosage form of a drug if a plan or insurer had previously approved coverage of the drug for a health condition, and a participating provider continues to prescribe the drug for the condition, if the drug, dosage, or dosage form of the drug was prescribed appropriately and is considered safe and effective for an insured's health condition under current generally accepted standards of care.

7) Indicates a prescription drug is prescribed appropriately if a provider is authorized to prescribe or furnish the drug within the provider's scope of practice, and this does not preclude a participating provider from prescribing or furnishing another drug that is clinically appropriate for an insured or prohibit generic drug substitution, as specified.

8) Applies 4) and 5) of "this bill" above to a prescription drug that was prescribed Off-label, as specified. Exempts a Medicare supplement policy or a specialized health insurance policy that covers only dental or vision benefits.

9) Repeals existing law that allows 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.

10) Makes denials of coverage on the basis of Off-label use of a prescription drug that is experimental, not clinically appropriate, or for any other reason, subject to IMR.

11) Permits the Insurance Commissioner to promulgate regulations subject to the Administrative Procedure Act to implement and enforce this bill.

12) Permits, in addition to any other remedies that are available to the Insurance Commissioner for a violation of this bill to enforce this article, as specified and indicates that this does not impair or restrict the commissioner's authority pursuant to another provision of this code or the Administrative Procedure Act.

Comments

According to the author, this bill strengthens California's prohibition on non-medical switching — when a health plan forces a patient to switch from a prescribed drug to a different drug for non-medical reasons — by clarifying that

the prohibition also applies to the dose level and dosage form of a previously prescribed drug. Health plans and insurance companies should not be able to disrupt a patient's care, risking severe pain and even death, to save money. This bill allows patients to continue on their medication, at their optimized dosage, to ensure continuity of care and prioritize the safety of those living with chronic illnesses.

California Health Benefits Review Program (CHBRP) analysis. AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996, and reviewed this bill.

Key findings include:

Assumptions. CHBRP assumes this bill would have no impact for plans without a regulated pharmacy benefit. A generic-only pharmacy benefit regulated by CDI or DMHC is not and would not be required to cover brand-name drugs. CHBRP assumes that Coverage of any medically necessary services associated with the administration of the drug for which the Off-Label mandate would require coverage is and would be required (as is specified in the Off-Label mandate). CHBRP assumes the prohibition on changing cost-sharing would apply during a plan/policy year but not if the enrollee changed to another plan or policy. Should this not be the case, impacts on premiums could become orders of magnitude greater than what is projected in this analysis.

Coverage. Under the altered Off-Label mandate, for which applicability would be unchanged: 5,173,000 enrollees would have enhanced coverage for Off-label use of dosages and dosage forms of prescription drugs. Under the altered Continuity mandate which would be applicable to the health insurance of 427,000 more enrollees: 5,173,000 enrollees would have enhanced coverage for continuing use of dosages, dosage forms, and Off-label use of prescription drugs; and 13,404,000 enrollees would have new
limits on cost-sharing (so long as they do not change to another plan or policy).

Utilization. At baseline, the total number of prescriptions filled for drugs impacted by this bill predominantly non-preferred brand and specialty drugs prescribed for Off-label use – would be 551,000. Should this bill be enacted, 4,000 additional prescriptions are projected to be filled, resulting from 18,000 fewer generic and preferred brand prescriptions filled and 22,000 more non-preferred brand and specialty prescriptions filled.

Expenditures. Without this bill, the average unit cost of a 30-day supply for a drug with coverage impacted by this bill is estimated to be approximately $2,908. Within this average, unit costs for particular drugs range from less than $750 to more than $6,000. If this bill is enacted, the average unit costs of impacted prescriptions would be 0.76% higher, not because the unit costs of the drugs would change, but with this bill because the mix of covered prescriptions filled would include a smaller proportion of generic and preferred brand drugs and a greater proportion of specialty and non-preferred brand drugs, which are generally more expensive.

Total net annual expenditures would increase by $27,070,000 (0.02%) for enrollees with health coverage subject to state-level benefit mandates. This includes an increase of $15,251,000 in premiums paid by employers and employees, and an increase of $7,734,000 in premiums paid by individuals and families, and another $4,085,000 in increased cost-sharing for covered benefits.

Although the altered Continuity mandate would limit cost-sharing, the Off-Label mandate, which would be connected to the majority of additional filled prescriptions, would not alter applicable cost-sharing. Under the altered Off-Label mandate, CHBRP projects increased utilization of specialty and non-preferred brand drugs, as well as Off-formulary drugs (all of which are often associated with greater per-fill cost-sharing) and therefore an increase in total enrollee cost-sharing due to greater use of prescriptions to which greater cost-sharing is applicable. Although CHBRP cannot estimate the frequency at which some enrollees may have self-paid for prescriptions at baseline, the high unit costs for many of the drugs would have limited self-pay at the population-level due to affordability.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Senate Appropriations Committee:

- The Department of Managed Health Care estimates costs for state administration to be approximately $2,159,000 in 2023-24, $3,139,000 in 2024-25, $3,447,000 in 2025-26, $3,776,000 in 2026-27, and $3,767,000 in 2027-28 and annually thereafter (Managed Care Fund).

- The Department of Insurance estimates costs for state administration to be $6,000 (Insurance Fund) in 2023-24.

- The California Health Benefits Review Program (CHBRP) estimates annual expenditures for CalPERS premiums would increase by $310,000.

SUPPORT: (Verified 5/19/23)

Crohn's & Colitis Foundation (source)
AFSCME
Biocom California
California Access Coalition
California Association of Orthodontists
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Orthopedic Association
California Pharmacists Association
California Retired Teachers Association
California Rheumatology Alliance
California School Employees Association
California State Association of Psychiatrists
Children's Specialty Care Coalition
Infusion Access Foundation
Lupus and Allied Diseases Association
National Multiple Sclerosis Society, MS-CAN
National Psoriasis Foundation
San Francisco Marin Medical Society
Spondylitis Association of America
Steinberg Institute
The Kennedy Forum
The Leukemia & Lymphoma Society

OPPOSITION: (Verified 5/19/23)

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

ARGUMENTS IN SUPPORT: This bill's sponsor, the Crohn's and Colitis Foundation, writes that under current law, health care plans cannot force patients to switch medication for non-medical reasons, such as financial incentives. However, this does not apply to the dose or dosage form of the same drug. This bill will protect patients by ensuring that the prescribed dose or dose level of the previously approved drug is protected under non-medical switching law. Many Californians who suffer from a 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. There is no one size fits all treatment for everyone with IBD. The approach must be tailored to the individual because each person's disease is different. 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. The California Medical Association writes when the renewal of medication is delayed, denied or not covered at the therapeutic dose or form, treatment can be disrupted, even if the prescription is ultimately approved on appeal. These disruptions can lead to severe, and sometimes irreversible, negative health outcomes in both adult and pediatric patients. Limiting access to medically necessary drugs, or covering a drug at an ineffective dose or form, is not appropriate or quality care. This can also lead to the development of antibodies and loss of response to the drug. Having access to the right medication, at the right time, and in the best dosage is essential for patients.

ARGUMENTS IN OPPOSITION: The California Association of Health Plans (CAHP), Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP) write that this bill would broadly dismantle existing utilization management processes for prescription drugs by nullifying these existing processes for any drug, dosage of a drug or dosage form of a drug indefinitely once it has been initially approved by the health plan. This bill effectively negates our ability to ensure clinically appropriate use of prescription drugs and would encourage the use of expensive specialty and brand name drugs when a generic or lower cost brand equivalent is available and clinically appropriate. This bill would also create potential patient safety concerns for enrollees. When health plans and insurers choose to limit or deny a drug or specific dose of a drug, it is generally for safety reasons. Specific reasons include potential abuse or overuse, inconsistency with FDA-approved labeling or to prevent use at doses that have not been studied or shown to be efficacious. This bill ignores these potential risk factors by allowing enrollees' unfettered access to prescription drugs if they have ever been approved for a certain drug. Simply put, if a health plan initially approves a drug to treat a certain condition, a provider can then change the dose or dosage form of that drug forever without any health plan oversight. CAHP, ACLHIC and AHIP are concerned that stripping health plans

and insurers of the ability to provide clinical oversight and access to certain drugs may cause potentially adverse reactions and real harm to enrollees. This bill will lead to potentially dramatic increases in health care costs in California. This bill would prohibit plans from adjusting the enrollee or insured's portion of the cost share if the drug had previously been covered, regardless of an increase in dosage or change in dosage form. Factoring in that CHBRP's analysis points to an increase in expenditures of $27 million just for the prohibition of cost-sharing attributed to the Off-label mandate, CAHP, ACLHIC and AHIP are very concerned that a permanent cap on all cost-sharing will have a significant impact on the affordability of health care coverage in the state.

Prepared by: Teri Boughton / HEALTH / (916) 651-4111
5/20/23 12:37:49

****** END ******