SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 853
AUTHOR: Wiener
VERSION: February 28, 2022
HEARING DATE: April 20, 2022
CONSULTANT: Teri Boughton

SUBJECT: Prescription drug coverage

SUMMARY: Prohibits a health plan contract or health insurance policy from limiting or excluding coverage for a dose of a drug on the basis that the dose prescribed is different from the dose that has been approved for marketing by the federal Food and Drug Administration, prohibits a health plan or insurance policy from limiting or excluding coverage for a dose of a drug, or dosage form for an enrollee or insured if the drug previously had been approved for coverage, provided the dose of the drug, or dosage form is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition, except if it is denied in the final utilization review, and, requires a drug, dose of drug, or dosage form to be covered during the entire utilization review period if previously approved by a plan or insurer.

Existing law:

1) Requires, under federal regulations, a group health plan and a health insurance issuer offering group or individual health insurance coverage to implement an effective internal claims and appeals process, and, requires continued coverage pending the outcome of an appeal. [45 CFR §147.136]

2) Requires, under federal regulations, if a group health plan has approved an ongoing course of treatment to be provided over a period of time or number of treatments, any reduction or early termination by the plan to constitute an adverse benefit determination, and requires notification and opportunity for appeal, and timely review, as specified. [29 CFR §2560.503-1]

3) Requires, under federal regulations, a health plan providing essential health benefits to have specific processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing and when calculating the plan's actuarial value. [Title 45 CFR §156.122(c)]

4) 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 insurers. [HSC §1340, et seq., and INS §106, et seq.]

5) 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 the expeditious process required in #11) below;
   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; and,
         (3) The Thomson Micromedex DrugDex; and,
   d) 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]

6) Requires any coverage required pursuant to 5) 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]

7) Defines "life-threatening" as either or both diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival. [HSC §1367.21 and INS §10123.195]

8) 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]

9) Requires every disability insurer that covers hospital, medical, or surgical benefits and health plan to provide an external, independent review process to examine the insurer's or plan's coverage decisions regarding experimental or investigational therapies for an individual with a life-threatening or seriously debilitating condition, as specified. [HSC §1370.4 and INS §10145.3]

10) 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 does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution.[HSC §1367.22]

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

12) Requires every health plan to establish and maintain a grievance 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]

13) 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, 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]

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

15) 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]

This bill:

1) Prohibits a health plan contract or health insurance policy from limiting or excluding coverage for a dose of a drug on the basis that the dose prescribed is different from the dose that has been approved for marketing by the FDA, provided specified conditions in existing law described in 5) above have been met.

2) Prohibits a health plan contract from limiting or excluding coverage for a dose of a drug, or dosage form for an enrollee if the drug previously had been approved for coverage, provided the dose of the drug, or dosage form is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition, except for any drug that is denied in the final utilization review pursuant to 3) below.

3) Requires a health plan contract or insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits, to provide coverage for a drug, dose of a drug, or dosage form during the entire duration of utilization review and any appeals of utilization review if that drug has been previously approved for coverage by a health plan for a medical condition of the enrollee or insured and has been prescribed by a health care provider.

4) Prohibits a health plan or insurer from seeking reimbursement from an enrollee/insured, health care provider, or other person for prescription drug coverage during utilization review if the final utilization review decision is to deny coverage for that prescription drug, dose, or dosage form.

5) Defines, "utilization review" as prospectively, retrospectively, or concurrently reviewing and approving, modifying, delaying, or denying, based in whole or in part on medical necessity, a request by a health care provider, enrollee, insured or authorized representative of a provider or enrollee or insured for coverage of a prescription drug.

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

COMMENTS:

1) *Author's statement.* According to the author, this bill ensures that patients receive prompt access to medication and that they aren't forced to go without medication during appeals of insurance denials. It does so by requiring health plans and insurers to cover a denied medication, a dose that a patient has previously been prescribed, or an optimized dose of a previously prescribed medication, for the duration of an appeals process. This bill also clarifies 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 prescribed dose or dose level of a drug. The bill prohibits plans from seeking reimbursement if a denial is sustained on appeal. By expanding this coverage and these protections, this bill strengthens patient stability and wellbeing. When health plans and insurers refuse to cover medications, those actions can pose life-threatening health challenges. At a time when COVID-19 infections continue to soar, it is particularly dangerous for Californians already living with chronic illnesses to be denied access to life-saving medications. This bill allows patients to continue on their medication, at their optimized dosage, during an appeals process to ensure continuity of care and prioritize the safety of those living with chronic illnesses.

2) *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. For its analysis, CHBRP has assumed that this bill's reference to "utilization review and any appeals of utilization review" would include: 1) Prior authorization review and response by the plan or insurer; 2) Appeal review and response by the plan or insurer; and, 3) Appeal review and response by the regulator (DMHC or CDI). After what would generally be one to three prescription fills during these three periods, utilization management techniques would be applicable, which would limit further impact of this bill. CHBRP has assumed that the additional prescriptions filled pursuant to this bill would be for a 30-day supply. This abbreviated analysis presents expected impacts on benefit coverage, utilization, and cost. Key findings include:

   a) *Coverage impacts and enrollees covered*. There are 5% of commercial and CalPERS enrollees in policies and plans regulated by CDI and/or DMHC that are without a pharmacy benefit regulated by CDI or DMHC, so this bill is not applicable to them. Of the remaining commercial/CalPERS enrollees, at baseline, none have benefit coverage

that is fully compliant with this bill. CHBRP's analysis indicates that approximately 13 million and 14 million enrollees depending on the provisions, post enactment would have coverage compliant with this bill.

b) *Utilization*. At baseline, the total annual number of prescriptions filled for drugs impacted (predominantly maintenance drugs with utilization review requirements) is 1,108,750. This figure represents less than 1% of prescriptions filled for enrollees with a pharmacy benefit regulated by DMHC or CDI. CHBRP estimates, if this bill were enacted, 22,851 additional prescriptions would be filled. This impact would primarily derive from the requirement that influence coverage for enrollees changing one plan or policy for another, a situation often referred to as enrollee "churn." CHBRP's analysis shows an increase of average unit cost of impacted prescriptions filled of $36**.**

c) *Medi-Cal.* Medi-Cal beneficiaries enrolled in DMHC-regulated plans have a pharmacy benefit but not one that is included their DMHC-regulated plan therefore this bill is not applicable to enrollees in Medi-Cal managed care**.**

d) *Medical effectiveness.* CHBRP indicates that the number of outpatient prescription drugs for which this bill could change access to coverage would be extremely large so no analysis of medical effectiveness could be completed within CHBRP's 60-day analytic period.

e) *Impact on expenditures*. This bill would increase total net annual expenditures by $83,735,000 (0.06%) for enrollees with health insurance subject to state-level benefit mandates. This is due to a $74,277,000 increase in total health insurance premiums and a $9,458,000 increase in enrollee cost-sharing. CHBRP projects no change to copayments or coinsurance applicable to filled prescriptions for particular drugs (which vary from plan to plan and from policy to policy). However, CHBRP does project an increase in utilization of specialty and brand drugs, as well as off formulary drugs (which are often associated with greater per-fill cost-sharing) and therefore an increase in total enrollee cost-sharing. Premiums would increase by $26,991,000 in the group market, and the greatest impact will be on individuals and families purchasing in the individual market where premiums are estimated to increase by .26% or $34,056,000**.**

f) *Essential health benefits.* As this bill would not require coverage for a new benefit mandate, the bill would not appear to exceed the definition of essential health benefits in California and would not require the state to defray its cost impacts.

3) *Related legislation.* AB 2352 (Nazarian) requires a health plan or health insurer to furnish specified information about a prescription drug upon request by an enrollee or insured, or their health care provider. Prohibits a health plan or health insurer from restricting a health care provider from sharing the information furnished about the prescription drug or penalizing a provider for prescribing a lower cost drug, as specified. *AB 2352 is pending in the Assembly Appropriations Committee.*

AB 742 (Nazarian of 2021) is substantially similar to AB 2352. *AB 742 was held in the Assembly Appropriations Committee.*

4) *Prior legislation.* 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. 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. 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. 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 a 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.

5) *Support.* According to the Chrohn's and Colitis Foundation, this bill's sponsor, California law already prohibits health plans from forcing patients to switch medications that were previously approved, which allows patients who are stable on a drug to remain on that medication, even if the health plan changes their preferred treatments. However, this law does not currently apply to dose or frequency of administration. Additionally, most prescriptions that are initially denied are ultimately approved when appealed. For example, in 2019, 87.5% of Inflammatory Bowel Disease patients who appealed their insurance medication denials through DMHC's IMR process eventually had their request approved. Unfortunately, during the IMR review, health plans are not obligated to cover the drug and since many patients do not know this appeal is available to them, they are often left without their necessary medication for a period of time, which may be lengthy, until a final decision is made. This bill rectifies these problems by allowing patients to stay on their previously approved medications, including an increase in the dose of that medication for the duration of the utilization review or any appeals. The bill also expands California's "non-medical switching" law to include dose, so that when a provider is requesting only an increase in the dose, or the frequency of administration, of an already approved drug, the patient is not required to wait for a new approval.

6) *Opposition.* The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans (opponents) write that this bill and thirteen other health insurance mandate bills will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options. Opponents indicate now is not the time to inhibit competition with proscriptive mandates that reduce choice and increase costs. In the face of continued uncertainty and efforts to fragment the market and promote less comprehensive coverage, California needs to protect the coverage gains we've made and stay focused on the stability and long-term affordability of our health care system. Benefit

mandates impose a one-size-fits-all approach to medical care and benefit design driven by the Legislature, rather than consumer choice. Benefit mandates that do not promote evidence-based medicine can lead to lower quality care, over- or misutilization of services, and higher costs for treatments that may be ineffective, less safe, or higher cost than other, new or trusted services. California is rightly focused on achieving both universal coverage and cost containment at a time when the national conversation has shifted toward lower costs through less comprehensive options. The California Chamber of Commerce writes CHBRP analyzed the cost impacts associated with this bill and concluded that if this bill went into effect, it would increase employer health care premiums by over $27 million. Employee premiums would increase over $9 million.

7) *Amendments.*

a) CDI has requested amendments to codify federal requirements, apply the bill to student health insurance, include mental health and substance use disorders in definition of chronic and seriously debilitating conditions, and remove an outdated provision.

b) It should be made clear that an enrollee or insured is subject to cost-sharing, if any, during utilization review.

c) The bill should be clarified to indicate that a final utilization review refers to IMR.

SUPPORT AND OPPOSITION:

Support: Crohn's & Colitis Foundation (sponsor)
American College of OB/GYN's District IX
Biogen
California Chapter of the American Cardiology College
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Pharmacists Association
California Podiatric Medical Association
California Retired Teachers Association
California Rheumatology Alliance
Children's Specialty Care Coalition
Depression and Bipolar Support Alliance
Infusion Access Foundation
National Multiple Sclerosis Society

Oppose: America's Health Insurance Plans
Association of California Life and Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce
One individual

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