

Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2000 (Aguiar-Curry) – As Amended March 9, 2026

SUBJECT: Drug formularies.

SUMMARY: Prohibits a health plan or health insurer that provides prescription drug benefits and maintains one or more drug formularies from making changes to a formulary during a plan or policy year, except in specified circumstances. Specifically, **this bill:**

- 1) Prohibits a health plan or insurer that provides prescription drug benefits and maintains one or more drug formularies from making changes to a formulary during a plan year, including removing a drug from a formulary, moving a drug to a higher cost tier, or imposing new utilization management requirements on a drug.
- 2) Provides exemptions to allow a health plan or insurer to make changes to a formulary for any of the following reasons:
 - a) To add a newly approved drug. Requires, if a generic drug is newly approved, the cost sharing for the newly approved generic drug to be lower than the brand name drug, but brand name drug coverage to not be removed until the end of the plan year;
 - b) To remove a drug due to safety concerns from the United States Food and Drug Administration (FDA);
 - c) To move a specified drug to a lower formulary tier or otherwise modify its formulary placement in a manner that reduces enrollee cost sharing; or,
 - d) To remove utilization management or prior authorization requirements for a covered drug.
- 3) Requires a health plan, insurer, or their pharmacy benefit manager (PBM) to report any changes made to a formulary during a plan year to the Department of Managed Health Care (DMHC) or California Department of Insurance (CDI) within 30 days of the change being made.
- 4) Requires a health plan or insurer to authorize appeals for coverage denials based on formulary changes through its existing internal and external appeals processes.
- 5) Allows DMHC and CDI to impose an administrative penalty for a violation of this section of not less than five hundred dollars (\$500) per 1,000 enrollees and up to five thousand dollars (\$5,000) per 1,000 enrollees.
- 6) Requires DMHC and CDI, when assessing administrative penalties, to determine the appropriate penalty amount for each violation based on one or more factors as applicable.
- 7) Requires, beginning January 1, 2030, and every five years thereafter, the penalty amounts specified in 5) above to be adjusted based on the average rate of change in premium rates for

the individual and small group markets, and weighted by enrollment, since the previous adjustment.

- 8) Requires penalties levied under this bill to be paid by the plan and not be paid by the provider, subscriber, or enrollee.
- 9) Permits DMHC and CDI to conduct audits that relate to this bill and are not based on an enrollee's complaint.

EXISTING LAW:

- 1) Establishes DMHC to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 and CDI to regulate health insurers. [Health and Safety Code (HSC) § 1340, *et seq.*, and Insurance Code (INS) § 106, *et seq.*]
- 2) Requires every health plan and insurer that maintains one or more drug formularies to:
 - a) Post the formulary or formularies for each product offered on their website in a manner that is accessible and searchable by potential and current enrollees or insureds, providers, the general public, DMHC and CDI, and federal agencies as required by federal law or regulations;
 - b) Update the formularies posted pursuant to a) with any change to those formularies on a monthly basis; and,
 - c) No later than six months after the date that a standard formulary template is developed under 3) below, use that template to display the formulary or formularies for each product offered by the insurer. [HSC § 1367.205 and INS § 10123.192]
- 3) Requires DMHC and CDI, by January 1, 2017, to jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template. In developing the template, requires DMHC and CDI to take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. Requires DMHC and CDI, to the extent feasible, in developing the template to evaluate a way to include on the template cost-sharing information for drugs subject to coinsurance. [*Ibid.*]
- 4) Requires the standard formulary template in 3) above to include a notification that the presence of a drug on the insurer's formulary does not guarantee that an insured will be prescribed that drug by his or her prescribing provider for a particular medical condition. Requires the standard formulary template to do all of the following:
 - a) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product;
 - b) Indicate any drugs on the formulary that are preferred over other drugs on the formulary;
 - c) Include information to educate insureds about the differences between drugs administered or provided under a health insurer's medical benefit and drugs prescribed under a health

- insurer's prescription drug benefit and about how to obtain coverage information about drugs that are not covered under the health insurer's prescription drug benefit;
- d) Include information to educate insureds that health insurers that provide prescription drug benefits are required to have a method for insureds to obtain prescription drugs not listed in the health insurer's drug formulary under existing law;
 - e) Include information on which medications are covered, including both generic and brand name; and,
 - f) Include information on what tier of the health insurer's drug formulary each medication is in. [*Ibid.*]
- 5) Defines "formulary" as the complete list of drugs preferred for use and eligible for coverage under a health care service plan product and includes the drugs covered under the pharmacy benefit of the product. [*Ibid.*]
- 6) Prohibits a health plan health, on or after July 1, 1999, 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 medical condition. Exempts drugs that are prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA. [HSC § 1367.22]
- 7) Requires every health plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. Requires, on or before July 1, 1999, every health plan that provides prescription drug benefits to file with DMHC a description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Requires any changes to this process to be filed with DMHC. Requires each plan to provide a written description of its most current process, including timelines, to its prescribing providers. [HSC § 1367.24]
- 8) Requires every health plan that provides prescription drug benefits and maintains one or more drug formularies to provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary of the plan by major therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs. Requires the health plan, if it maintains more than one formulary, to notify the requester that a choice of formulary lists is available. [HSC § 1367.20]
- 9) Allows health plans to require step therapy if there is more than one clinically appropriate drug, including requiring an enrollee to try an AB-rated generic equivalent, biosimilar, or interchangeable biological product before providing coverage for the equivalent branded prescription drug. Patients can request an exception. [HSC § 1367.206]
- 10) Requires health plans to cover at least one FDA-approved medication in several categories of opioid use disorder treatment without step therapy, prior authorization, or utilization review, and allows for these to be AB-rated generic equivalents, biosimilars, or interchangeable biological products. [HSC § 1342.75]

- 11) Establishes the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and dangerous drug or device wholesalers, and establishes the Board of Pharmacy (Board) to enforce the Pharmacy Law. [Business and Professions Code (BPC) § 4000, *et seq.*]
- 12) Authorizes a pharmacist filling a prescription for a drug product to select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy, unless the prescriber indicates either orally or in their own handwriting, "Do not substitute" or words of similar meaning. Authorizes a prescriber to check a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark. Specifies that selection of a different form of medication is within the discretion of the pharmacist and that they assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. Specifies that there is no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this authority. In the event of substitution, requires the patient to be informed that a different form of medication is used and requires the prescription label to include the name of the dispensed drug product. Prohibits substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients. [BPC § 4052.5]
- 13) Further authorizes a pharmacist, when filling a prescription for a drug product prescribed by its trade brand name, to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the FDA, of those drug products having the same active chemical ingredients. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 12) above. Prohibits a pharmacist from substituting unless the drug product the pharmacist selects costs the patient less than the prescribed drug product. Clarifies that cost includes any professional fee charged by the pharmacist. Specifies that these requirements apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program. [BPC § 4073]
- 14) Authorizes a pharmacist filling a prescription for a prescribed biological product (as defined by federal law) to select an alternative biological product if the alternative biological product is interchangeable and if the prescriber does not indicate "Do not substitute" or words of similar meaning. Requires, within five days following the dispensing of a biological product, a dispensing pharmacist or their designee to make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. Requires an entry that can be electronically accessed by the prescriber through various electronic records systems and specifies that entering the information into an electronic records system is presumed to provide notice to the prescriber. In the event a pharmacist does not have access to any of the various electronic records systems, authorizes the pharmacist or their designee to communicate the name of the biological product via fax, telephone, electronic transmission, or other means but the communication is not required if there is no

FDA approved interchangeable biological product or if the refill is not changed from the product dispensed on the prior filling. Outlines the same “Do not substitute” specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 12) above. Outlines the same cost specifications in 13) above. [BPC § 4073.5]

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

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, this bill prohibits health plans and PBMs from changing prescription drug coverage midyear, protecting patients from unexpected costs and treatment disruptions. The author states that this bill ensures Californians may continue needed medications, especially for chronic or serious conditions, without interruption. The author continues that this bill also brings greater clarity and predictability to coverage, helping patients plan and budget for care. The author concludes that by safeguarding access to essential medications, this bill supports continuity of treatment, reduces administrative burdens on providers, and strengthens patient protections.
- 2) **BACKGROUND.** Health plans have a list of drugs they have already approved for coverage. This list is called a formulary. Formularies are a tool used by plans to adapt to the evolving landscape of pharmacy products. With the rise of high-cost and specialty drugs, formulary management can be leveraged as a strategy to manage costs for the plan and enrollee while optimizing enrollee access to a range of prescription drugs.
 - a) **Rising Prescription Drug Spending and SB 17 Report.** In 2021, the U.S. spent an average of \$691 more per person on retail pharmaceuticals, over-the-counter drugs, and medical equipment than comparable countries. From 2020 to 2023, national retail prescription drug spending rates increased by 8.6%, following a 3.3% increase in average annual growth the decade before, outpacing spending growth on hospitals or physicians and clinics. When drug prices increase, these costs get passed to employers and health plan enrollees via increased premiums. The 2025 California Health Benefits Survey reports that 36% of large California companies (over 200 employees) report that prescription drug prices contributed “a great deal” to higher premiums, including 63% of companies with 5,000 or more workers. SB 17 (Hernandez), Chapter 603, Statutes of 2017 requires health plans in the commercial market to annually report their prescription drug costs to the DMHC. This report looks at the impact of the cost of prescription drugs on health plan premiums and compares this data across the reporting years. The cost of prescription drugs continues to impact the affordability of health care overall, with health plans paying about \$14.9 billion for prescription drugs in 2024. Prescription drug costs have increased at a higher rate compared to medical expenses and health plan premiums. Total prescription drug costs increased by 9.5% in 2024, whereas total medical expenses increased by 6.9% and health plan premiums increased by 8% from 2023 to 2024. Specialty drugs and brand name drugs are primary drivers of the increase in total prescription drug-cost spending. Brand name drugs account for only 9.4% of all prescriptions dispensed but accounted for 25.2% of total annual spending on prescription drugs. In contrast, generic drugs accounted for 88.8% of all prescriptions but only 11.8% of the total annual spending on prescription drugs. According to the DMHC, health plans

paid almost \$1.3 billion more on prescription drugs in 2024 than in 2023. Since 2017, total prescription drug costs paid by health plans increased by \$6.2 billion or 72%.

- b) Current Avenues to Promote Adoption of Lower-Cost Drugs.** Given that prescription drugs, particularly brand name and specialty drugs, are a leading driver in skyrocketing health care costs – legislators, consumer advocates, and health plans have been pushing policy reforms to increase the adoption of generics, biosimilars, and other lower-cost drugs. Under existing state law, when a drug product is prescribed by its brand name, a pharmacist may select an equivalent drug product with the same active ingredient, strength, and dosage form, unless the prescribing provider indicates “Do not substitute.” This authority applies at the time of dispensing and permits the pharmacist, in their professional discretion, to select among therapeutically equivalent products, including substituting a generic drug for a brand-name drug, and interchangeable biosimilar for a brand-name biologic, or dispensing products from different manufacturers over time, provided that the substituted product complies with applicable equivalence, labeling, and cost requirements. Pharmacies routinely dispense an FDA-approved equivalent product that is covered or preferred by a patient’s health plan, which can result in patients receiving different generic versions across refills. The pharmacist is dispensing a therapeutically equivalent drug product rather than altering the prescription itself. SB 1094 (Weber Pierson) of this year is proposing to expand this law to allow pharmacists to substitute brand name biologics for any biosimilar, not just those deemed interchangeable.

While enrollees choose a plan for the plan year, changes in what is covered, health plan contracts, new prescription drugs and uses, and more can happen at any time of the year. Health plans and PBMs negotiate their drug contracts and formularies throughout the year, not only at the beginning of the plan year. Although some formulary changes may be disruptive for patients and providers, many of these changes mean there is a more affordable drug available, a different use for a drug, or a new generic or biosimilar has come to market. To allow plans to maintain formulary negotiating flexibility while ensuring patient continuity of care, existing law prohibits health plans from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for their medical condition. Existing law also requires health plans to maintain a process for providers to request authorization to prescribe a medically necessary prescription drug that isn’t on their formulary.

- 3) SUPPORT.** The California Academy of Family Physicians (CAFP) is sponsoring this bill, stating that patients choose health plans during open enrollment partly based on which medications are covered and the costs associated with those drugs. CAFP continues that mid-year formulary changes, such as removing drugs, increasing cost-sharing, or adding new prior authorization or step therapy requirements, can leave patients without access to the treatments they depend on. CAFP argues that these changes are often driven by financial considerations rather than clinical need and can result in medication disruptions, worsening health outcomes, and increased health care utilization. CAFP notes that for physicians, these shifts also create a significant administrative burden, requiring time-consuming prior authorization requests for treatments that were already deemed medically necessary, ultimately taking time away from patient care. CAFP continues that this bill provides an important safeguard by requiring health plans to honor the coverage and cost-sharing terms in place at the start of the plan year. CAFP concludes that by preventing mid-year formulary

changes while allowing patient-centered exceptions, this bill promotes continuity of care, protects patients from unexpected costs, and reduces unnecessary administrative hurdles for physicians.

- 4) **SUPPORT IF AMENDED.** Health Access supports this bill if amended. Health Access supports the intent of the bill to ensure continuity of care for consumers when there are changes to the formulary during the health plan, however they want to ensure that consumers are able to benefit from cost savings that health plans are able to secure mid-year as soon as possible. Health Access is requesting amendments that would narrow the prohibition on changes during the year, allow for further exceptions to the prohibition and other changes that would ensure more affordable and the best quality care for consumers. Health Access notes that existing law allows for substitutions for the generic for the brand name drug to ensure cost-savings for consumers. When a generic comes to market, the pharmaceutical company typically increases the price of the brand name drug and marketing to consumers and prescribers for the product one to two years leading up to it. That is why Health Access requests removing the requirement to keep the brand name drug on the formulary for the rest of the plan year. Health Access notes that this aligns with existing law that prioritizes ensuring consumers are prescribed the generic of the drug that is more affordable. With the same goal, Health Access proposes a similar exception for biosimilars and interchangeable biologics that would result in lower cost-sharing for the consumer. Health Access further requests amendments removing the prohibition on removals of drugs from the formulary and new utilization management during the plan year to ensure that consumers see the benefits of health plan negotiations for more affordable drugs for the formulary or research changes on prescription drugs. Health Access provides an example of changes that benefit consumers is if a drug is found to treat a condition different than manufactured for. Health Access concludes that their amendments would ensure that changes in the formulary that would benefit consumers would still be allowed and further continuity of care protections.
- 5) **OPPOSITION.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) are strongly opposed to this bill, stating that it would fundamentally undermine their ability to ensure patient safety, respond to emerging clinical data, and manage the skyrocketing costs of prescription drugs. CAHP and ACLHIC continue that by "freezing" formularies mid-year, this bill inadvertently protects pharmaceutical manufacturer profits at the expense of California consumers and employers. CAHP and ACLHIC note that this bill restricts a plan's ability to act swiftly when new clinical evidence emerges. While the bill provides limited exceptions for FDA mandated removals, it ignores the reality that health plans and insurers are often the first to identify safety issues through real-world data. CAHP and ACLHIC continue that the bill's current language restricts the adoption of lower-cost alternatives, which is the primary driver of prescription drug savings for consumers. CAHP and ACLHIC note that "egregious" administrative penalties and audit authority in this bill far exceed any reasonable standard. CAHP and ACLHIC are deeply concerned by the provision that would make a willful violation a crime, creating a state-mandated local program for what are essentially clinical and fiscal management decisions. CAHP and ACLHIC conclude that this bill would freeze California's health care system in a way that prevents health plans and insurers from adopting evidence-based treatment.

The Pharmaceutical Care Management Association (PCMA) is also opposed to this bill, because it would limit a PBM's ability to manage drug formularies, one of the most

important tools for lowering prescription drug costs by holding drug manufacturers accountable. PCMA continues that big pharma regularly increases list prices, often drastically and without justification or advance notice to plans. PCMA argues that PBM tools, including formulary management, are used to protect employers and patients from these increases. PCMA states that the National Academy of Science, Engineering and Technology notes that formulary controls help keep premiums low, formulary management best practices can reduce costs by roughly 10% compared to an unmanaged benefit. PCMA concludes that as written, this bill will only encourage drug manufacturers to increase drug prices mid-year and remove incentives to offer discounts, knowing a plan must cover a drug, regardless of a more cost-efficient alternative becoming available.

- 6) **RELATED LEGISLATION.** SB 1094 (Weber Pierson) would authorize a pharmacist to select an alternative biological product for a prescribed biological product if it is a biosimilar. Would authorize health plans and insurers to require enrollees to try a therapeutically equivalent generic, biosimilar, or interchangeable biological product if the prescriber has not indicated “Do not substitute” and when the generics or biosimilars are covered by the health plan or insurer and available to the enrollee at the same or lower cost. AB 1094 is currently pending in the Senate Health Committee.

7) **PREVIOUS LEGISLATION.**

- a) SB 671 (Hill), Chapter 545, Statutes of 2015 authorizes a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the alternative biological product is designated as interchangeable with the reference product, among other conditions, and communication is provided to the patient and physician that a substitution was made. It also requires the Board of Pharmacy to maintain a link on its internet website to the list of biological products recognized as interchangeable by the FDA.
- b) SB 598 (Hill) of 2013 would have authorized pharmacists to substitute a biosimilar for a biologic under specified circumstances, including a requirement that notification of the substitution be provided, and defined “biological product,” “biosimilar,” and “interchangeable.” SB 598 was vetoed by Governor Brown who noted that “CalPERS and other large purchasers warn that the requirement itself would cast doubt on the safety and desirability of more cost-effective alternatives to biologics....The FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for “interchangeability.”
- c) AB 1139 (Lowenthal) of 2013 would have authorized a pharmacist to substitute a biosimilar for a biological product if the product is deemed by the FDA to be interchangeable with the biological product. AB 1139 was held in the Assembly Business and Professions Committee.

- 8) **PROPOSED AMENDMENTS.** To address concerns on the proposed formulary limitations contributing to the rising cost of drugs and care while balancing the need to ensure access to medically necessary care for consumers, the author and committee have agreed to amendments to do the following:

- a) Remove prohibition on changes in utilization management and removal of prescription drugs from the formulary during the plan or policy year;

- b) Remove the requirement that a brand name drug remain on the formulary for the entirety of a plan or policy year;
- c) Ensure formulary change exemptions for generic additions also apply to biosimilars;
- d) Ensure health plans and insurers can add any drug, not just newly approved drugs, to their formulary. Clarify that if a drug is replacing a previously covered drug in the same drug class during the plan year that it must result in the same or lower cost sharing;
- e) Clarify that existing law allows consumers to remain on a drug that was previously covered by DMHC regulated plans, provided that the drug is appropriately prescribed and considered safe and effective for treating the enrollee's medical condition;
- f) Require a plan or insurer to notify a consumer and the prescribing provider if they plan to implement a formulary change that will require the consumer to change to a different drug in the same drug class during the plan year no less than 90 days before the formulary change is implemented. Requires the notification for DMHC regulated plans to include information on continuity of previously covered drugs as noted in e) above;
- g) Update existing law requiring plans to maintain an expeditious process for requests to cover nonformulary drugs. Require the expeditious process to follow the same timelines as prior authorization requests. Require a plan to provide 90 days of transitional coverage for a requested drug, if the timelines are not met;
- h) Require DMHC to leverage existing data and authority to collect data on enrollee requests for coverage of nonformulary drugs, any denials/appeals of those requests, and outcomes of disputes; and,
- i) Permit DMHC and CDI to investigate and take enforcement against noncompliance with this bill, require notification and the opportunity for a hearing prior to assessing penalties.

REGISTERED SUPPORT / OPPOSITION:

Support

California Academy of Family Physicians (sponsor)
Association for Clinical Oncology
California Chronic Care Coalition
California Life Sciences Association
Crohn's and Colitis Foundation
National Health Law Program

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans
Pharmaceutical Care Management Association

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