Date of Hearing: June 27, 2023

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 70 (Wiener) – As Amended April 18, 2023

SENATE VOTE: 31-9

SUBJECT: Prescription drug coverage.

SUMMARY: Prohibits a health plan or insurer from limiting or excluding coverage of a drug, dose of a drug, or dosage form of a drug that is prescribed for off-label use if the drug has been previously covered for a chronic condition or cancer, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary. Prohibits a health plan contract or health insurance policy from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. Specifically, **this bill**:

Off-label Provisions

1) Prohibits a health plan contract or insurance policy from limiting or excluding coverage for a drug, dose of a drug, or dosage form of a drug on the basis that the drug, dose of a drug, or dosage form is prescribed for a use, dose, or dosage form that is different from the use, dose, or dosage form for which the drug has been approved for marketing by the United States Food and Drug Administration (FDA) if all of the following conditions have been met:
   a) The drug is approved by the FDA;
   b) One of the following is true:
      i) The drug, dose, or dosage form is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or,
      ii) The drug, dose, or dosage form is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition and the drug, dose, or dosage form is medically necessary to treat that condition.
   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;
         (3) The Thomson Micromedex DrugDex.
      iii) 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.
   d) The drug has been previously covered for a chronic condition or cancer.

Continuity Provisions

2) 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 for a drug, dosage of a drug, or dosage form of a drug if the 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.

3) Prohibits a health plan contract or insurance policy from imposing additional cost sharing not already imposed, for a drug, dose of a drug, or dosage form for an enrollee or insured 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, dose of the drug, or dosage form is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. Prohibits this bill, with respect to cost sharing, from being construed to affect application of a deductible or coinsurance, or cost-sharing changes associated with contract changes at renewal. Allows the plan to charge additional cost sharing associated with that tier if the change of dosage or dosage form results in coverage of a drug in a higher tier. Applies to a prescription drug that is prescribed off-label, as specified in existing law.

4) Authorizes the California Department of Insurance (CDI) Commissioner to promulgate regulations subject to the Administrative Procedure Act to implement and enforce this bill, as specified.

5) Makes other technical and conforming changes.

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 and CDI to regulate health insurance. [Health and Safety Code (HSC) §1340, *et seq*., Insurance Code (INS) §106, *et seq*.]

2) Establishes as California's essential health benefits (EHBs) benchmark the Kaiser Small Group Health Maintenance Organization, existing California mandates, and 10 federal Patient Protection and Affordable Care Act mandated benefits, including prescription drugs. [HSC §1367.005 and INS §10112.27]

3) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review (UR) or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:
   a) Be developed with involvement from actively practicing health care providers;
   b) Be consistent with sound clinical principles and processes;
   c) Be evaluated, and updated if necessary, at least annually;
   d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
   e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

4) Requires reviews, for purposes of Independent Medical Review (IMR), to determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee or insured and any of the following:
   a) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;

b) Nationally recognized professional standards;
c) Expert opinion;
d) Generally accepted standards of medical practice; or,
e) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious. [HSC §1374.33 and INS §10169.3]

5) 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]

6) Authorizes a health plan or insurer that provides coverage for prescription drugs to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition. [HSC §1367.206 and INS §10123.201]

7) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the applicable time limit described in 5) above if a prescribing provider submits necessary justification and supporting clinical documentation that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, taking into consideration the enrollee's or insured's needs and medical history. Permits the basis of the provider's determination to include, but not be limited to, any of the following criteria:

   a) The prescription drug required by the plan or insurer is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm in comparison to the requested prescription drug;
   b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee or insured and the known characteristics and history of the enrollee's or insured's prescription drug regimen;
   c) The enrollee or insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. Permits the plan or insurer to require the submission of documentation demonstrating that the enrollee or insured tried the required prescription drug before it was discontinued;
   d) The required prescription drug is not clinically appropriate for the enrollee or insured because the required drug is expected to do any of the following, as determined by the prescribing provider:
      i) Worsen a comorbid condition;
      ii) Decrease the capacity to maintain a reasonable functional ability in performing daily activities; or,
      iii) Pose a significant barrier to adherence to, or compliance with, the enrollee or insured's drug regimen or plan of care.
   e) 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 and INS §10123.201]

8) Authorizes a health care provider or prescribing provider, enrollee, insured, or their designee or guardian to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the plan's or insurer's current UM process. [HSC §1367.206 and INS §10123.201]

Off-label Provisions

9) Prohibits a health plan contract or insurance policy from being issued, amended, delivered, or renewed if the plan or insurer limits or excludes 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 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,
   c) 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;
   d) 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.
      iii) 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 §1367.22]

Continuity Provisions

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. Does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution, as authorized. Specifies that provisions do not apply to coverage for any 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 in 9) above. [HSC §1367.22]

FISCAL EFFECT: According to the Senate Appropriations Committee:

1) DMHC 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);

2) CDI estimates costs for state administration to be $6,000 (Insurance Fund) in 2023-24; and,

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

COMMENTS:

1) PURPOSE OF THIS BILL. 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. The author concludes that 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.

2) BACKGROUND.

a) Prescription drug coverage. According to CHBRP, 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 (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 UM techniques, (including prior authorization, step therapy, and formulary requirements) to off-label use of a drug, dosage, or dosage form. 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, as may be the case for off-label use of a drug or continued coverage for a drug that is no longer expected to be covered for the enrollee. Plans and insurers regulated by DMHC and CDI must complete 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 – DMHC or CDI – for state regulated health insurance. The regulator may uphold the denial or may require the plan or insurer to cover the drug.

b) Off-Label and Continuity Provisions of California Law. CHBRP notes that the term off-label refers to use of a drug in a way that differs from the specifications explicitly approved by the FDA. The FDA's specifications may include particular drug dosages (a measurement, often in milligrams) or particular dosage forms (oral vs. inhaled, extended vs. immediate release, ocular vs. oral, etc.). California law requires that plans and policies that include a pharmacy benefit not exclude a drug from coverage because the drug is

being prescribed off-label when: i) the drug is prescribed by a contracting prescriber; and, ii) when specified criteria are met. California law also requires coverage of any medically necessary services associated with the administration of the drug for which the California law would require coverage. This bill expands the off-label requirement from "drug" to "drug, dose of the drug, or dosage form."

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 from "drug" to "drug, dose of the drug, or dosage form"; specifies that the requirement apply to off-label use of a drug, so long as the criteria in the off-label mandate are met; and, prohibits cost sharing changes if the drug had already been covered.

c) 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. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP states the following in its analysis of this bill:

i) **Utilization.** Under the proposed off-label provisions of this bill, for which applicability would be unchanged, CHBRP notes that 5,173,000 enrollees would have enhanced coverage for off-label use of dosages and dosage forms of prescription drugs. Under the proposed continuity provisions which would be applicable to the health insurance of 427,000 more enrollees, CHBRP notes that 5,173,000 enrollees would have enhanced coverage for continuing use of dosages, dosage forms, and off-label use of prescription drugs; and 3,404,000 enrollees would have new limits on cost sharing (so long as they do not change to another plan or policy). At baseline, the total number of scripts filled for drugs impacted by this bill, predominantly non-preferred brand and specialty drugs prescribed for off-label use, would be 551,000. Postmandate, 4,000 additional scripts are projected to be filled, resulting from 18,000 fewer generic and preferred brand scripts filled and 22,000 more non-preferred brand and specialty scripts filled. At baseline, 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. Postmandate, the average unit costs of impacted scripts would be 0.76% higher, not because the unit costs of the drugs would change, but because the postmandate mix of covered scripts 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.

ii) **Impact on expenditures.** This bill would increase total net annual expenditures by $27,070,000 (0.02%) for enrollees with health insurance subject to state-level

benefit mandates. Although the proposed continuity provisions would limit cost sharing, the off-label provisions, which would be connected to the majority of additional filled scripts, would not alter applicable cost sharing. Under the off-label provisions, 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 scripts to which greater cost sharing is applicable. Although CHBRP cannot estimate the frequency at which some enrollees may have self-paid for scripts at baseline, the high unit costs for many of the drugs would have limited self-pay at the population-level level due to affordability.

iii) CHBRP Assumptions: CHBRP has made a number of analytic assumptions, including:

(1) Should the prohibition on cost sharing be applicable on a year-over-year basis, and/or should it be applicable after an enrollee changes plan or policy, CHBRP notes that impacts on premiums could, in the long term, become orders of magnitude greater than what is projected in this analysis. For the continuity provision of this bill, the prohibition on cost sharing change is applicable only within a plan/policy year; and, does not apply if the enrollee changed to another plan or policy.

(2) This bill would have no impact for plans without a regulated pharmacy benefit.

3) SUPPORT. The Crohn's & Colitis Foundation (CCF) write that 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. 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. Most prescriptions 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. However, 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. IBD is just one of many chronic illnesses for which an inadequate dose can cause serious of 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. CCF concludes that limiting access to medically necessary drugs and drug dosage is not adequate and does not represent quality care.

4) **OPPOSITION**. The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans, write that this bill will indefinitely limit a health plan or insurer's ability to review any changes that are made to an existing prescription including off label use with respect to managing the dosage of the medication and/or the dosage form. This bill effectively negates the opponent's 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.

   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've ever been approved for a certain drug. The opponents 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. Lastly, this bill will lead to potentially dramatic increases in health care costs in California. Specifically, 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. Notably, the CHBRP analysis points to a key assumption that this specific provision would not apply if an enrollee or insured changed to another plan or policy and would reset during a plan/policy year. In conversations with the author's office as well as the sponsors, the opposition understand these assumptions are not reflective of their intent, but rather, that the prohibition on cost sharing is meant to apply on a year-over-year basis, effectively making the cost sharing prohibitions for these individuals permanent. Critically, CHBRP states in their analysis that if the prohibition on cost sharing were to be permanent, that impacts on premiums could, in the long term, become "orders of magnitude greater than what is projected in this analysis." 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, the opposition is concerned that a permanent cap on all cost sharing will have a significant impact on the affordability of health care coverage in the state.

5) **RELATED LEGISLATION**.

   a) SB 339 (Wiener) requires a health plan and health insurer to cover preexposure prophylaxis (PrEP) and postexposure prophylaxis furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist, and reimburse pharmacist services at 100% of the fee schedule for physician services. Includes PrEP furnished by a pharmacist as pharmacist services on the Medi-Cal schedule of benefits. Authorizes a pharmacist to furnish up to a 90-day course of PrEP, or beyond a 90-day course (existing law allows for a 60-day supply), if specified conditions are met. SB 339 is pending in Assembly Health Committee.

   b) SB 427 (Portantino) prohibits a health plan or health insurer from subjecting antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the federal Centers for Disease Control and Prevention for the prevention of *HIV/AIDS*, to prior authorization or step therapy, but authorizes prior authorization or step therapy if at least one therapeutically equivalent version is covered

without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. SB 427 is pending in Assembly Health Committee.

c) SB 873 (Bradford) requires an enrollee's or insured's defined cost sharing for each prescription drug to be calculated at the point of sale based on a price that is reduced by an amount equal to 90% of all rebates received, or to be received, in connection with the dispensing or administration of the drug. Requires a health plan or insurer to, among other things, pass through to each enrollee or insured at the point of sale a good faith estimate of the enrollee's or insured's decrease in cost sharing. Requires a health plan or health insurer to calculate an enrollee's or insured's defined cost sharing and provide that information to the dispensing pharmacy, as specified. SB 873 is pending in Assembly Health Committee.

6) PREVIOUS LEGISLATION.

a) SB 853 (Wiener) of 2022 would have prohibited a health plan or disability 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. 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. Would have required a plan or insurer that has approved an ongoing course of treatment to provide continuing coverage pending appeal or review. 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 died in the Assembly Appropriations Committee.

b) 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.

c) AB 1268 (Rodriguez) of 2019 would have required a health plan or health insurer, on or before July 1, 2020, and annually on July 1 thereafter, to report to the appropriate department the number of times in the preceding calendar year that it approved or denied each of the 30 health care-services for which prospective review was most frequently requested. AB 1268 was held on suspense in the Assembly Appropriations Committee.

d) AB 1353 (Waldron) of 2017 would have required a health plan and health insurer that provides coverage for outpatient prescription drugs to establish an expeditious process, as described, by which enrollees and insureds, enrollees' and insureds' designees, or

prescribing providers may request and obtain an exception to any prior authorization process or any other utilization management or medical management practices utilized by the plan or health insurer for medically necessary prescription drugs, and would have required a plan or health insurer to grant an exception request under these provisions under specified circumstances to ensure continuity of care for an enrollee or insured who is medically stable and was either previously prescribed the prescription drug within 100 days prior to enrollment or if, within 100 days prior to the exception request, the prescription drug was previously approved for coverage by the plan or insurer for the same medical condition. AB 1353 was never heard in Assembly Health Committee.

e) AB 2752 (Nazarian) of 2016 would have required a health plan or a health insurer to annually notify an enrollee or insured that the enrollee's or insured's drug treatment or provider is no longer covered by the plan or policy. AB 2752 was held in Assembly Appropriations Committee.

f) AB 2400 (Nazarian) of 2016 would have required health plans and health insurers to comply with a shortened internal grievance review process for formulary drugs. AB 2400 was held in Assembly Appropriations Committee.

g) AB 374 (Nazarian), Chapter 621, Statutes of 2015, authorizes a request for an exception to a health care service plan's or health insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization for prescription drugs. Requires the health plan or insurer to treat, and respond to, the request in the same manner as a request for prior authorization for prescription drugs.

h) AB 339 (Gordon), Chapter 619, Statutes of 2015, requires health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretrovirals drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of Human immunodeficiency virus infection and acquired immune deficiency syndrome, as specified. Codifies in state law, federal requirements related to pharmacy and therapeutics committees, access to in-network retail pharmacies, standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California and copayment caps of $250 and $500 for a supply of up to 30 days for an individual prescription, as specified.

7) AUTHOR'S AMENDMENTS. The author proposes the following amendments to address CDI technical assistance:

a) Require the participating prescriber's request to be considered pursuant to the prior authorization request specified in existing law if the drug is not on the insurer's formulary; and,

b) Specify that in the case of the dose or dosage form of the drug, the drug was previously covered off-label for a chronic condition or cancer.

8) POLICY COMMENT.

a) Author's Intent. This bill prohibits a health plan or insurer from imposing additional cost sharing for a drug, dose of a drug, or dosage form for an enrollee or insured if the drug has previously been approved for coverage. As noted above, CHBRP assumes (and calculated expenditures based on this assumption) that the continuity provisions of this bill only applies during a current plan year and does not carry over into a new plan year. As this bill moves forward, the author may wish to clarify this bill's intent and whether or not this prohibition is applicable into a new plan year as this could change the costs of this bill.

b) Affordability. CHBRP notes that this bill would increase total net annual expenditures by $27,070,000. Under the off-label provisions, 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 scripts to which greater cost sharing is applicable. CHBRP's analysis additionally notes that given the variation and the large number of potentially impacted drugs, CHBRP cannot estimate likely per-user enrollee impacts. The author may wish to consider the unintended consequences of the increased utilization of pricier specialty and non-preferred brand drugs and potential impact of higher out of pocket costs to enrollees.

REGISTERED SUPPORT / OPPOSITION:

Support

Crohns and Colitis Foundation (sponsor)
AFSCME
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Pharmacists Association
California Retired Teachers Association
California School Employees Association
Children's Specialty Care Coalition
Hemophilia Council of California
Infusion Access Foundation (IAF)
National Multiple Sclerosis Society
San Francisco Marin Medical Society
Steinberg Institute
The Leukemia & Lymphoma Society

Opposition

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

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