SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: AB 1880
AUTHOR: Arambula
VERSION: April 19, 2022
HEARING DATE: June 15, 2022
CONSULTANT: Teri Boughton

SUBJECT: Prior authorization and step therapy.

SUMMARY: Requires a health plan or insurer to ensure a clinical peer reviews an appeal of a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request. Requires plans and insurers to maintain specified information related to their use of step therapy and prior authorization and make it available to the Department of Managed Care and the Department of Insurance upon request.

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 insurance. [HSC §1340, et seq. and INS §106, et seq.]

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

3) Requires, if a health plan or insurer, contracted physician group, or utilization review organization fails to notify a prescribing provider of its coverage determination within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization or step therapy exception request, the prior authorization or step therapy exception request to be deemed approved for the duration of the prescription, including refills. [HSC §1367.241 and INS §10123.191]

4) Requires a health plan or health insurer to expeditiously grant a request for a step therapy exception within time frames described in 3) above if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the plan or insurer required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee or insured, taking into consideration the enrollee's or insured's needs and medical history, along with the professional judgment of the enrollee's or insured's provider. Establishes allowable criteria relevant to the provider's determination. [HSC §1367.206 and IC §10123.201]

5) Requires a policy of health insurance that covers outpatient prescription drugs to cover medically necessary drugs. Permits the policy to provide for step therapy and prior authorization consistent with the Knox-Keene Act related to prescription drug coverage requirements.[INS §10123.201]

This bill:

1) Requires a health plan's or health insurer's utilization management process to ensure that an appeal of a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request is reviewed by a clinical peer who had no involvement in the initial coverage determination that is the subject of the appeal nor is the subordinate of an individual who made the initial coverage determination.

2) Requires a health insurer's internal appeal process related to the appeals and requests described in 1) above to also be reviewed by a clinical peer as described above.

3) Defines "clinical peer" to mean a physician or other health professional who holds an unrestricted license or certification from any state and whose practice is in the same or a similar specialty as the medical condition, procedures, or treatment under review.

4) Requires every health plan or health insurer that requires step therapy or prior authorization to maintain, at a minimum, all of the following information, and that the information be made available to DMHC and CDI, in a deidentified format, designated by DMHC and CDI, upon request:

    a) The number of exception requests for coverage of a nonformulary drug, step therapy exception requests, and prior authorization requests received.

    b) The type of health care providers and medical specialties of the health care providers submitting requests, and the type of health care providers and medical specialties of the health care providers reviewing initial requests and internal appeals.

    c) The number of exception requests for coverage of a nonformulary drug, step therapy exception requests, and prior authorization requests that were initially denied and the reasons for the denials.

    d) The number of exception requests for coverage of a nonformulary drug, step therapy exception requests, and prior authorization requests that were initially approved.

    e) The number of denials of requests for coverage of a nonformulary drug, step therapy exception requests, and prior authorization requests that were appealed internally and sent to external review, as well as the number upheld and reversed by an internal appeal or an external review.

    f) The time elapsed between a step therapy exception request and approval, including initial approval or approval granted through an internal appeal or an external review.

FISCAL EFFECT: According to the Assembly Appropriations Committee,

1) Costs of $64,000 in fiscal year (FY) 2022-23 and $71,000 in FY 2023-24 to CDI (Insurance Fund) to review health insurance utilization review policies and procedures for compliant language and develop and/or revise existing regulations as required by this bill.

2) DMHC estimates the total cost of this bill to be approximately $478,000 in FY 2022-23, $1.5 million in FY 2023-24, $3.6 million in FY 2024-25 and $1.2 million in FY 2025-26 and thereafter (Managed Care Fund). DMHC indicates these costs are for reviewing Evidence of

Coverage documents, provider contracts, plan-to-plan contracts and other health plan documents for compliance with the requirements in this bill; workload associated with increased volume of consumer complaints; short-term workload to conduct legal research and promulgate a regulation; workload to review health plan filings of utilization management data and procedures and modernizing the eFile system and building a data mart for analytics and reporting. According to DMHC, the recently amended version of this bill may result in slightly lower, though still significant, costs.

COMMENTS:

1) *Author's statement.* According to the author, AB 347 (Arambula, Chapter 743, Statutes of 2021), established a process to connect patients on step therapy with the right medicine for them. This bill builds upon AB 347 by ensuring patients who are denied coverage of critical medication have their appeals reviewed by a physician with the necessary knowledge. Further, this bill establishes data collection requirements to track and evaluate the implementation of AB 347.

2) *Step therapy.* According to CMS.org, step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. For example, using step therapy plans could ensure that a senior who is newly diagnosed with a condition begin treatment with a cost-effective biosimilar before progressing to a more costly drug therapy should the initial treatment be ineffective. The California Health Benefits Review Program (CHBRP) glossary describes step therapy as a utilization management protocol where payment for a drug is restricted unless certain other drug therapies have been tried first. These programs are sometimes referred to as fail-first requirements since a certain drug cannot be prescribed until other therapies have been tried first and shown to be ineffective.

3) *Prior authorization.* According the CHBRP glossary, prior authorization is when the health plan or pharmacy benefit manager must authorize a particular prescription before it can be filled. Prior authorization also may be used in conjunction with a step therapy system, so that a patient might be required to try a less expensive drug before receiving authorization to receive the drug originally requested.

4) *Related legislation.* SB 250 (Pan) establishes a process for "deemed approved" status for individual health professionals' prospective treatment utilization review required by health plans and health insurers. *SB 250 is pending in the Assembly Health Committee.*

   SB 999 (Cortese) requires the DMHC and CDI to adopt rules for utilization review for mental health and substance use disorder treatment related to reviewer qualifications and disclosures, and telephone and peer access during authorization requests. *AB 1880 is set to be heard in the Assembly Health Committee on June 28, 2022.*

5) *Prior legislation.* AB 347 (Arambula, Chapter 743, Statutes of 2021) sets up a timeline for approval or denial of step therapy exception request for prescription drugs based on the timeline for prior authorization requests for prescription drugs, and permits a health plan and health insurer to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition, but creates an exception request under certain circumstances such as if the enrollee or insured has tried the health plan/insurer required drug or another prescription drug in the same pharmacologic class and it was

discontinued due to lack of efficacy or effectiveness or an adverse reaction. Makes several other changes to law with regard to prior authorization and step therapy exceptions, and grievance and external appeal requirements.

6) *Support.* The Crohn's & Colitis Foundation (foundation), one of this bill's sponsors, writes that this bill ensures that the peer with whom a physician speaks is a physician practicing the same specialty and subspecialty as the ordering physician. The foundation knows the physicians assigned by the health plans to conduct clinical reviews, often general practitioners, are often capable physicians. However, they have not been trained or have not had the experience needed to understand medical necessity for treatments that are rare or specialized. Without this specialized experience, patients could be at risk of developing dangerous complications and requiring new medical interventions that will ultimately lead to additional costs to the system. The clinical peer review process, as used today, is hurting patient outcomes and ultimately adding cost to the system. This bill also ensures that the state departments have the ability to request health plans and insurers keep information regarding their use of utilization management protocols. This includes information such as how often step therapy and prior authorization requests are denied and for what reasons they are being denied. As the Legislature and the departments consider legislation and regulation of utilization management protocols in the future, having this type of information will greatly assist in policy making. The Arthritis Foundation, another cosponsor, writes this bill would help ensure that a clinical peer makes the step therapy exception and prior authorization decisions on behalf of health plans. The California Rheumatology Alliance, another cosponsor, writes many times Rheumatologists are having their denials reviewed by physicians who have no experience in treating rheumatology patients. It is critical when a physician is reviewing a denial, they understand the patient's condition in order to make an educated determination over whether the appeal should be granted. The National Multiple Sclerosis (MS) Society writes that although insurers often defend the use of step therapy protocols as a method to ensure that safe, appropriate, and affordable drugs and treatments are provided to patients, patients, including people living with MS, and healthcare providers have voiced concerns regarding its potential adverse effects. Step therapy protocols transition medical decisions from a shared decision-making approach between the provider and the patient towards more standardized policies that focus on cost-effective care. These policies may not consider the need to tailor care to individual patient needs, factoring in efficacy, dosage, route of administration, and side effects. For those with diseases such as MS, prolonging ineffective treatment and delaying access to the right treatment may result in disease progression, relapses and worsening disability, or other damage from the disease.

7) *Opposition.* The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans write that last year, health plans and insurers successfully worked with stakeholders to address several policy and implementation concerns with AB 347 related to step therapy exceptions, and are disappointed to see that many of these policy concerns have reemerged in this bill, which will only lead to negative outcomes and increased costs for consumers. Health plans and insurers use step therapy for prescription drugs to control health care costs and ensure patient safety. This bill subjects health plans and insurers to onerous reporting requirements despite the presence of existing law and robust regulations addressing this issue.

8) *Oppose unless amended.* The California Chamber of Commerce (Chamber) writes that it is unclear how this new requirement would be implemented. Health plans and insurers would either need to hire clinical peers and this process would drive costs upward. Reviewing

physicians would likely charge rates that are commensurate with their clinical rates considering the review time would force the providers to sacrifice time away from treating their patients. The Chamber requests these portions be removed from this bill. The Chamber states this bill requires plans and insurers to create and retain new data and reports that are onerous and would force plans and insurers to design new administrative processes. This will increase costs which will be passed on to premium paying employers and employees.

9) *Policy comment.* The data identified in this bill could be helpful to policymakers as they evaluate the many proposals introduced to limit health plan utilization management programs. The committee may wish to also have the denial data by medical specialty and/or service or treatment type, if possible. It is also unclear what the expectations are for plans and insurers to "maintain" this data and for how long.

SUPPORT AND OPPOSITION:

Support: Arthritis Foundation (co-sponsor)
California Rheumatology Alliance (co-sponsor)
Crohn's & Colitis Foundation (co-sponsor)
Alliance for Patient Access
Association for Clinical Oncology
Biogen
California Council of Community Behavioral Health Agencies
California Chronic Care Coalition
California Academy of Family Physicians
California Life Sciences
California Pharmacists Association
California Society of Plastic Surgeons
Chronic Disease Coalition
Crohn's and Colitis Foundation
Looms for Lupus
Lupus Foundation of America, Southern California
Movement Disorders Policy Coalition
National Multiple Sclerosis Society
National Organization for Rare Disorders
Steinberg Institute

Oppose: America's Health Insurance Plans
Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce (unless amended)

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