Date of Hearing: April 11, 2023

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 1437 (Irwin) – As Introduced February 17, 2023

SUBJECT: Medi-Cal: serious mental illness.

SUMMARY: Prohibits treatment authorization requests (also known as prior authorization, or PA) for drugs prescribed for serious mental illness (SMI). Specifically, **this bill**:

1) Prohibits a treatment authorization request from being required for the provision of a prescription drug prescribed to prevent, assess, or treat an SMI.

2) Requires a prescription for a drug for SMI to automatically be approved if Department of Health Care Services (DHCS) verifies a record of a paid claim that documents a diagnosis of an SMI within 365 days before the date of that prescription.

3) Applies 1) and 2), above, only if both of the following conditions are met:
   a) The prescription is for a person 18 years of age or over; and,
   b) The person is not within the transition jurisdiction of the juvenile court, as specified.

4) Defines SMI as a mental disorder that is identified in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders and that is severe in degree and persistent in duration, presents a major risk to the person's health and well-being, causes behavioral functioning that interferes substantially with the primary activities of daily living, and results in an inability to maintain stable adjustment and independent functioning without treatment, support, and rehabilitation for a long or indefinite period of time. States SMI may include, but is not limited to, schizophrenia, post-traumatic stress disorder, bipolar disorder, other major affective disorders, or other severely disabling mental disorders.

EXISTING LAW:

1) Establishes the Medi-Cal Program, administered by DHCS, to provide comprehensive health benefits to low-income individuals who meet specified eligibility criteria. [Welfare and Institutions Code (WIC) § 14000 *et seq*.]

2) Establishes a schedule of benefits under the Medi-Cal program, including prescription drugs, subject to the Medi-Cal contract drug list (CDL) and utilization controls. [WIC §14132]

3) Requires DHCS, when evaluating a decision to execute a contract with a drug manufacturer, and when evaluating drugs for retention on, addition to, or deletion from the CDL to use all of the following criteria:
   a) The safety of the drug;
   b) The effectiveness of the drug;
   c) The essential need for the drug;
   d) The potential for misuse of the drug; and,
   e) The cost of the drug. [WIC §14105.39]

4) Limits the utilization controls that may be applied to the Medi-Cal services set forth in existing law, but authorizes prior authorization as one of the authorized utilization controls. [WIC §14133]

5) Defines prior authorization:
   a) As approval by a DHCS consultant, of a specified service in advance of the rendering of that service based upon a determination of medical necessity; and,
   b) To include authorization for multiple services which are requested and granted on the basis of an extended treatment plan where there is a need for continuity in the treatment of a chronic or extended condition. [WIC §14133]

6) Requires DHCS to determine which of the utilization controls are to be applied to a specific service or group of services that are subject to utilization controls, and requires each utilization control to be reasonably related to the purpose for which it is imposed. [WIC §14133]

7) Requires DHCS, for drugs covered under Medi-Cal requiring prior authorization, to ensure the timely and efficient processing of authorization requests by doing all of the following:
   a) Providing a response by telephone or other means of telecommunication within 24 hours of the receipt of an authorization request; and,
   b) To the extent permitted by federal law, providing for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation, as defined by federal regulation. [WIC §14133.37]

8) Requires, pursuant to Medi-Cal regulation, a treatment authorization request received by DHCS from a fee-for-service (FFS) Medi-Cal provider to be reviewed for medical necessity only. [California Code of Regulations, Title 22, §51003]

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, this bill will improve access to crucial medications for Medi-Cal patients with SMI by removing unnecessary barriers.

2) BACKGROUND.

a) Medi-Cal Prescription Drug Coverage. Outpatient prescription drug coverage is an optional benefit under federal law that all state Medicaid programs provide. Effective January 1, 2022, Medi-Cal provides outpatient prescription drug coverage through a statewide system called Medi-Cal Rx, via contract with a fiscal intermediary, Magellan Medicaid Administration, Inc. Even though the majority of individuals enrolled in Medi-Cal receive health care services through a managed care plan, the statewide Medi-Cal Rx system pays directly for all prescription drugs dispensed by a pharmacy and billed on a pharmacy claim.

Medi-Cal Rx maintains a single, statewide, approved Medi-Cal CDL that standardizes the Medi-Cal pharmacy benefit. The CDL is DHCS' preferred set of covered drugs and generally includes drugs for which there is a current state supplemental drug rebate agreement in place. Most drugs on the CDL do not have a PA requirement. Alternatively,

if a drug is not listed on the Medi-Cal CDL, it generally requires an approved PA for coverage.

b) PA. PA is commonly used by health care payers, including in public programs and commercial health plans. PA requirements are used to help control costs and ensure payment accuracy by verifying that an item or service is medically necessary, meets coverage criteria, and is consistent with standards of care before the item or service is provided. PA generally involves submission of administrative and clinical information by the treating physician. According to the Kaiser Family Foundation (KFF), in a 2021 American Medical Association Survey, most physicians (88%) characterized administrative burdens from this process as high or extremely high. Doctors also indicated that PA often delays care patients receive and results in negative clinical outcomes. KFF indicates PA is an increasingly scrutinized practice, and debate over further standards to limit the use or regulate PA may involve tradeoffs between claims spending versus access to care for patients and administrative burden for providers.

In Medi-Cal, certain pharmacy drug and medical supplies dispensed by a pharmacy are subject to PA by Medi-Cal Rx before reimbursement can be approved. A prescriber's office or pharmacy can submit an electronic PA request through a portal, other electronic means, or fax. Per state law, Medi-Cal Rx responds to PA requests within 24 hours (or the next business day if request is received after-hours). The Medi-Cal provider will receive a confirmation and/or notice of approval, deferral, modification, and/or denial, from DHCS.

DHCS indicates both initial and reauthorization PA requests are adjudicated based on documentation of medical necessity for the use of the specific medication requested. DHCS indicates documentation of medical necessity can be supported by including lab values, results of testing, treatment plan and treatment outcomes.

c) Medi-Cal Rx Reevaluation of PA. DHCS is currently implementing and evaluating changes to reduce the need for manual review and reduce administrative work associated with PA. As part of Medi-Cal Rx, DHCS states it is considering expanding auto-adjudication functionalities (i.e., automated claim approval and payment) to reduce the number of drugs with PA requirements that require manual review. DHCS lists potential categories of drugs for which it is considering expanding auto-adjudication. The list includes selective serotonin reuptake inhibitors (SSRIs) used to treat depression, but does not include antipsychotics commonly used to treat other SMIs.

On March 23, 2023, DHCS released a policy bulletin entitled, "Extended Duration Prior Authorizations for Maintenance Medications." DHCS indicates to reduce administrative burden while ensuring continued medication safety for beneficiaries, the department has enabled extended duration/multi-year PAs for up to five years for certain maintenance medications used for chronic conditions. This extended duration PA is provided for certain maintenance medications with a PA requirement. Additional restrictions such as quantity limits, age limits, diagnosis restrictions, and other clinical edits may apply. DHCS indicates for a maintenance medication with an approved PA or paid claims history within the 15-month lookback period, if a drug is eligible for extended duration PA, the prescription will be automatically extended. Antidepressants and antipsychotics are cited as examples of drug classes of maintenance drugs DHCS will evaluate for

extended duration PA, but DHCS has not yet made available the "Medi-Cal Rx Extended Duration Prior Authorization List" that will list specific eligible drugs.

d) Evidence of the Effects of Formulary Restrictions. Studies have examined the effectiveness and unintended consequences of PA and other restrictions for drugs generally, as well as drugs prescribed to treat SMI.

A June 2009 study in the journal *Psychiatric Services* entitled "Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings From Ten States" compared medication access problems among psychiatric patients in 10 state Medicaid programs, assessed adverse events associated with medication access problems, and determined whether prescription drug utilization management is associated with access problems and adverse events. Over 4,800 psychiatrists from the American Medical Association's Masterfile were randomly selected, 62% responded and 32% treated Medicaid patients and were randomly assigned a start day and time to report on two Medicaid patients. The results of the study found that a medication access problem in the past year was reported for a mean of 48.3% of the patients, with a 37.6% absolute difference between states with the lowest and highest rates. The most common access problems were not being able to access clinically indicated medication refills or new prescriptions because Medicaid would not cover or approve them (34%), prescribing a medication not clinically preferred because clinically indicated or preferred medications were not covered or approved (29.4%), and discontinuing medications as a result of prescription drug coverage or management issues (25.8%).

Medication access problems varied by state. The states with the lowest rates of reported medication access problems were New York (27.1%), Texas (31.0%), and California (32.4%), while Tennessee (63.3%), Georgia (64.2%), and Michigan (64.7%) had the highest rates. Patient access to new medications and medication refills also varied by state. Patients in New York, Texas, and California had the lowest rates of problems accessing clinically indicated medication refills or new prescriptions because they were not covered or approved (19.0%–22.4%), while patients in Tennessee, Georgia, and Michigan had the highest rates of problems (49.3%–55%).

e) Evidence of the Effects of Formulary Restrictions on Drugs Prescribed to Treat SMI. An issue brief by the University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics in 2015 summarized findings from three studies published in peer-reviewed journals that reviewed pharmacy claims for people with schizophrenia and bipolar disorder across 24 state Medicaid programs. The studies estimated the impact of formulary restrictions on health care spending and medication adherence. The studies included 117, 908 patients with schizophrenia and 170,596 people with bipolar disorder who were newly prescribed one of five atypical antipsychotics—olanzapine, risperidone, quetiapine, aripiprazole or ziprasidone. They examined formulary restrictions, defined as prior authorization and step therapy. According to the issue brief, patients with schizophrenia subject to formulary restrictions were more likely to experience a hospitalization, had 23% higher inpatient costs and had 16% higher total medical costs. Similar results were found for patients with bipolar disorder. Formulary restrictions were not associated with statistically significantly lower pharmacy expenditures for either group. Additionally, patients with schizophrenia subject to formulary restrictions had worse adherence.

A 2012 report from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, examined state Medicaid program polices for PA and copayments for drugs to treat schizophrenia and bipolar disorder. It found copayments and PA requirements for certain types of prescription drugs were associated with worse medication continuity even after accounting for several other Medicaid program and beneficiary characteristics. The report recommended that states should carefully consider the impact PA requirements and copayment amounts have on the ability of certain populations to receive continuous medications that help beneficiaries maintain their stability and avoid hospitalization. It also noted prior studies have found that PA policies may prevent Medicaid beneficiaries with bipolar disorder from filling prescriptions for antipsychotics and anticonvulsants, and that poor medication continuity is associated with relapses and costly hospitalizations among individuals with SMI. It suggests states may consider exempting these beneficiaries or certain medications from PA and copayment requirements.

f) **Proposed Federal Rule**. In December 2022, the Centers for Medicare and Medicaid Services published a proposed rule designed to reduce the administrative burden of PA by requiring certain payers to implement an automated process, meet shorter time frames for decision making, and improve transparency. The rule would apply to Medicaid programs and other public health insurance programs. Among other things, the rule would require payers to publicly report specific PA metrics annually. Impacted payers would be required to disclose annually on their website a list of all services requiring prior authorization and specific aggregated metrics. Metrics would include, among other items, the percentage of prior authorizations that were approved and denied, the percentage of prior authorization requests approved after appeal, and the average time for a prior authorization determination.

3) **SUPPORT**. This bill is sponsored by the California Access Coalition (CAC) and Psychiatric Physicians Alliance of California (PPAC) which argue that this bill will improve access to critical medications for Medi-Cal patients with SMI by removing unnecessary barriers. CAC and PPAC argue ensuring this population has uninterrupted access to prescribed medication to stabilize their mental health condition is more crucial than ever as the state attempts to address homelessness amid the COVID-19 pandemic. The sponsors state that studies of state Medicaid programs found psychiatric patients' lack of access to these medications contributes to a higher rate of negative outcomes for this population including increased emergency room visits, hospitalizations, homelessness, or incarceration. In addition, these negative outcomes are further exacerbated across racial and ethnic demographics. Sponsors note in California, 32.4% of psychiatric patients reported at least one medication access problem and 57.9% experienced an access problem that led to a negative outcome.

4) **RELATED LEGISLATION.**

a) AB 931 (Irwin) prohibits a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2025, that provides coverage for physical therapy, from imposing PA for the initial 12 treatment visits for a new episode of care for physical therapy. AB 931 is pending in the Assembly Health Committee.

b) AB 1288 (Reyes) prohibits health plans and insurers from subjecting a buprenorphine product, methadone, or long-acting injectable naltrexone for detoxification or

maintenance treatment of a substance use disorder that is prescribed according to generally accepted national professional guidelines for the treatment of a substance use disorder to PA. AB 1288 is pending in the Assembly Health Committee.

c) SB 324 (Limón) prohibits a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after January 1, 2024, from requiring PA or other utilization review for any clinically indicated treatment for endometriosis, as determined by the treating physician and consistent with nationally recognized evidence-based clinical guidelines. SB 324 is pending in the Senate Health Committee.

d) SB 427 (Portantino) limits a health plan or insurer's ability to impose PA and other utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the U.S. Food and Drug Administration or recommended by the federal Centers for Disease Control and Prevention for the prevention of AIDS/HIV. SB 427 is pending in the Senate Health Committee.

e) SB 598 (Skinner) prohibits, on or after January 1, 2025, a health plan or insurer from requiring a contracted health professional to complete or obtain a PA for any covered health care services if the plan or insurer approved or would have approved not less than 90% of the prior authorization requests they submitted in the most recent one-year contracted period, as specified. SB 598 is pending in the Senate Health Committee.

5) PREVIOUS LEGISLATION.

a) AB 1178 (Irwin) of 2021 would have prohibited PA from being required by the DHCS for a drug prescribed for the treatment of SMI for a period of 180 days after the initial prescription has been dispensed, required DHCS to automatically approve a prescription for a drug for the treatment of a SMI if the patient was previously dispensed that drug before they enrolled in the Medi-Cal program and during the previous 365 days of the date of the new prescription before the date of that prescription, and addressed early refills and 90-day supplies of drugs. AB 1178, similar to this bill, only applied for a person over 18 years of age and who is not under the transition jurisdiction of the juvenile court. AB 1178 was held on the Suspense File of the Assembly Appropriations Committee.

b) AB 3285 (Irwin) of 2020 was substantially similar to AB 1178. Due to the shortened Legislative calendar brought on by the COVID-19 pandemic, AB 3285 was not set for a hearing.

6) AMENDMENTS. Although evidence suggests states should carefully consider the effects of PA for drugs to treat SMI, a blanket prohibition on PA would limit the state's authority to examine clinical appropriateness of drugs to treat SMI, with unknown future consequences. To address policy concerns with a blanket prohibition, following discussions between committee staff, the author's office, and proponents, the author has agreed to delete the blanket prohibition on PA and narrow this bill to focus on prohibiting PA refills on a drug for SMI, in order to ensure continuity of drug access for individuals stabilized on a particular drug, as follows, and make conforming technical changes:

14133.19. (a) ~~Notwithstanding any other law, subject to subdivision (c), a treatment authorization request shall not be required for the provision of a prescription drug prescribed to prevent, assess, or treat a serious mental illness.~~

Notwithstanding any other law, subject to subdivision (~~c~~***b***), a prescription ***refill*** for a drug for serious mental illness shall automatically be approved ~~if the department verifies a record of a paid claim that documents a diagnosis of a serious mental illness within 365 days before the date of that prescription~~ ***for a period of 365 days after the initial prescription has been dispensed.***

REGISTERED SUPPORT / OPPOSITION:

Support

California Access Coalition (cosponsor)
Psychiatric Physicians Alliance of California (cosponsor)
Alliance for Patient Access
California Chronic Care Coalition
California Coalition for Mental Health
California Life Sciences
California State Association of Psychiatrists
Connection Coalition
DBSA California
Mental Health America of California
National Association of Social Workers, California Chapter
Pathpoint
Schizophrenia & Psychosis Action Alliance
Steinberg Institute
The California Association of Local Behavioral Health Boards and Commissions
The Kennedy Forum

Opposition

None on file.

Analysis Prepared by: Lisa Murawski / HEALTH / (916) 319-2097