

“Antipsychotics are dangerous.”

General

- This bill does not change evidence-based prescribing of any medication.
- This bill only makes a small tweak to the rules, alerts and guidelines already in place for Medi-Cal patients who are prescribed antipsychotics (see below).
- Many patients with serious mental illness struggle with activities of daily living, so it is particularly unreasonable to make it harder for these patients to access their medication.
 - Nothing in this bill changes the requirement for a health care provider to request and receive approval to prescribe a drug that requires prior authorization the first time an antipsychotic medication is prescribed.

California-specific

- Medi-Cal has rules, alerts and clinical guidelines in place related to psychotropic medications that this bill **will not change**:
 - [Prospective DUR alert for medication interactions with certain drugs and antipsychotics](#) “Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties.”
 - [TAR required for antipsychotic prescribed for patient 0-17](#) “An approved Treatment Authorization Request is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age. In addition, DHCS Pharmacy Benefits Division, DHCS Behavioral Health Division, and California Department of Social Services (CDSS) continue to collaborate on a Quality Improvement Project entitled, “Improving the Use of Psychotropic Medication among Children and Youth in Foster Care.” The purpose of this program is to reduce the rate of antipsychotic polypharmacy, improve the rate of compliance with age-specific antipsychotic dose recommended guidelines, and improve the rate of children and youth in foster care with at least one psychotropic medication who have an annual metabolic risk assessment. The goals are to reduce polypharmacy and improve compliance with dosing guidelines and annual metabolic risk assessment.
 - [TAR required for antipsychotic prescribed for beneficiaries in skilled nursing facilities](#) “Current restrictions in place to limit the quantity of antipsychotics include an approved Treatment Authorization Request is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age. An approved Treatment Authorization Request is also required for beneficiaries residing in skilled nursing facilities (SNFs).”
 - [Concomitant Anticholinergic and Antipsychotic Use Clinical Review Update 8/30/19](#) “Decisions regarding the prophylactic use of anticholinergic medications to prevent EPS should be determined on a case-by-case basis, in consideration of both patient-specific and medication-specific factors. In general, for patients taking second-generation antipsychotics with lower propensity for EPS, prophylactic anticholinergic medications are not recommended.”
 - [Atypical Antipsychotics and Adverse Metabolic Effects 4/29/2016](#) Clinical Recommendations: “Prescribe atypical antipsychotics for FDA-approved indications.

Address modifiable risk factors (smoking, obesity, lack of physical activity, unhealthy diet) in patients with mental illness even in the absence of metabolic changes. Primary care and mental health providers should communicate frequently for early detection of adverse metabolic effects and to minimize duplicate laboratory monitoring/workup.”

This bill aims to improve care for an already vulnerable population by reducing medication access problems that can lead to increased ER visits, hospitalizations and homelessness

- In [California](#), **32.4%** of patients with a psychiatric diagnosis reported **at least one medication access problem** in a study of 10 Medicaid programs.
- Psychiatric patients who experience treatment access problems are more likely to need to go to the ER, be hospitalized or become homeless compared to patients with consistent access to their medicine (based on a [study](#) of 10 state Medicaid programs, including Medi-Cal)
 - Psychiatric patients were **3.6 times** more likely to experience any adverse event including **emergency visits, hospitalizations, homelessness, suicidal ideation or behavior**; and
 - Were **3.2 times** more likely to be **homeless** if they discontinued or temporarily stopped taking their medication because of prescription drug coverage, utilization management or copayment issues
- According to the [California Department of Health Care Services](#) (DHCS), “Antipsychotic medications have proven to be effective in treating this disorder and adherence to schizophrenia medication keeps symptoms under control and prevents relapse.”
- In a [study](#) of treatment adherence for psychiatric medications among individuals experiencing homelessness **refill nonadherence rate was 47.1%**

Adherence is so important to maintaining care standards for people with serious mental illness, quality measures have been established to monitor patients’ access to antipsychotic meds

The National Committee for Quality Assurance (NCQA) is an U.S. organization that works to improve health care quality, in part by developing and maintaining a set of quality measures known as the Healthcare Effectiveness Data and Information Set (HEDIS). The HEDIS measures are used for performance improvement in health plans. HEDIS measures are developed for significant public health issues to set standards, track performance improvement, and monitor success of various initiatives.

- There are two HEDIS measures Medi-Cal has adopted related to adults prescribed antipsychotics. These are listed below along with NCQA’s explanation of why it matters:
 1. [Adherence to Antipsychotic Medications for Individuals with Schizophrenia \(SAA-AD\)](#)
“**Medication nonadherence is common and a major concern** in the treatment of schizophrenia. Using antipsychotic medications as prescribed reduces the risk of relapse or hospitalization.”
 2. [Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications \(SSD-AD\)](#)
“Lack of appropriate care for diabetes and cardiovascular disease for people with schizophrenia or bipolar disorder who use antipsychotic medications can lead to worsening health and death. **Addressing these physical health needs** is an important way to improve health, quality of life and economic outcomes downstream.”

*****Note: This measure only requires screening **once per year**, not more frequently.**

- HEDIS measures related to antipsychotics prescribed for children include:

[Use of Multiple Concurrent Antipsychotics in Children and Adolescents \(APC\)](#)

“Children and adolescents prescribed antipsychotics are at risk for serious health concerns. This includes weight gain, extrapyramidal side effects, hyperprolactinemia and some metabolic effects.”

****Note: This is why there is a TAR for patients 0-17. This bill does not change that.*

[Metabolic Monitoring for Children and Adolescents on Antipsychotics \(APM\)](#)

Antipsychotic “medications can increase a child’s risk for developing serious metabolic health complications associated with poor cardiometabolic outcomes in adulthood. Given these risks and the potential lifelong consequences, metabolic monitoring is important to ensure appropriate management of children and adolescents on antipsychotic medications.”

****Note: This measure only requires screening **once per year**, not more frequently.*

(“Assesses the percentage of children and adolescents with ongoing antipsychotic medication use who had metabolic testing during the year.”)

This bill would allow health providers to circumvent metabolic monitoring requirements

- As noted in the quality measures listed above, as well as the clinical guidelines published by [Medi-Cal](#), baseline assessment and monitoring for metabolic effects is recommended for patients who have been prescribed an antipsychotic.
 - Notably, the recommendations for this monitoring are separate from the prior authorization process.
 - Even the TAR for prescribing antipsychotics to patients under 17 y.o. does not require information on this kind of monitoring (see attached TAR).
- This type of metabolic monitoring is usually part of a primary care provider’s typical patient check-up. For example, [researchers from UCSF](#), in examining Medi-Cal enrollees prescribed an antipsychotic medicine found, “Among those who had at least 1 primary care visit during the year, the proportion screened (**annually**) was significantly higher at 35.6% vs 19.8% for those who had no primary care visit.”
- Even if prescribers of psychotic medications were required to perform these important metabolic tests, it would not be required for most patients more frequently than **annually**, and would not be part of the TAR process.

These are “minor administrative barriers that don’t justify removing the “safeguards” of prior auth”

- For patients with SMI, obtaining a prior authorization for a drug that has already been prescribed is not a “minor administrative barrier.” As the research above shows, non-adherence can cause several kinds of adverse effects for patients.
- Specific to the Medi-Cal program, as an example, in the [4th quarter of 2019](#), of the 64,140 alerts providers received related to underutilization (late refill) of an Rx, nearly 80% of those alerts were for mental health drugs, mostly antipsychotics. This means patients who have already cleared the prior authorization process in order to access their medication are struggling with refilling their medicine. **THESE ARE THE PATIENTS THIS BILL SEEKS TO HELP.**
- Even the Medi-Cal Drug Utilization Review (DUR) board considers these TARS as more than “minor barriers”

- In a Review of Board Action Items from November 27, 2018, during the [May 21, 2019](#) meeting, “Dr. Stafford commented the TAR process remains a burden...”
- “Dr. Stebbins motioned that the top drugs on the TAR list be reviewed again to identify how many TARs are due to being over the six prescription maximum. The motion was amended to also include the top three reasons for denials among antipsychotic medications.”
- In a review of this action item during the Medi-Cal DUR [September 17, 2019](#) meeting:
 - “Dr. McBride asked what percentage of all TARs is due to the statutory limit.”
 - “Mr. Garlick stated approximately 20% of TARs are due to the six prescription limit.”
 - “Dr. Stafford asked if any of the MCPs have similar TAR requirements based on the total number of prescriptions and the consensus at the meeting was that no MCPs have similar restrictions. Mr. Walker stated he would support efforts to remove this restriction in the fee-for-service population.”
 - Dr. Wong asked what could be done to update the law, especially since many times pairs of medications are needed and should be considered as one medication instead of two.”
 - “Dr. Stafford stated that the number of steps a patient needs to go through to get access is a large source of dissatisfaction for Medi-Cal providers”
 - Dr. Stafford “noted that in the absence of evidence that there is a direct benefit to limiting the number of prescriptions, the Board should go beyond asking DHCS staff to investigate this issue.”
 - Dr. Garrett reported that South Carolina had a similar policy, and a subsequent investigation convinced the legislature that the negative outcomes and barriers to care as a result of the prescription limit outweighed any financial benefit to the state.”
- The DUR created an ACTION ITEM: The DUR Board recommendation to investigate options to remove the TAR requirement for > 6 prescriptions, including policy workarounds will be submitted to DHCS.

How many patients is this bill likely to affect?

According to the latest information from the [Med-Cal DUR Board](#), there were:

- 15.3 million people eligible for Medi-Cal
- 4.5 million Medi-Cal enrollees (30%) had a paid pharmacy claim
- Of the Top 20 Drug Therapeutic Categories by Number of Claims:
 - Antipsychotics were **not in the Top 20** when considering the total Medi-Cal population
 - Antipsychotics were **not in the Top 20** when considering the Optional Targeted Low Income Children (OTLIC) population
 - Antipsychotics ranked 6 of 20 when considering the Seniors and Persons with Disabilities (SPD) population (62,449)
 - In total, an antipsychotic was used at least once by about **200,000 Medi-Cal enrollees**