

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 112

INTRODUCER: Health Policy Committee; Senators Harrell; and Wright

SUBJECT: Step-therapy Protocols

DATE: February 22, 2023

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	Fav/CS
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 112 creates an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product that is prescribed for the treatment of a serious mental illness, as that term is defined in the bill, or a medication of a similar drug class if prior authorization was previously granted for the prescribed drug and the medication was dispensed to the patient during the previous 12 months.

The bill directs the Agency for Health Care Administration (AHCA) to include the bill's rate impact on new managed care plan payment rates within Statewide Medicaid Managed Care that take effect October 1, 2023.

The bill provides an effective date of October 1, 2023.

II. Present Situation:

Florida Medicaid Program

Florida Medicaid is the health care safety net for low-income Floridians. The national Medicaid program is a partnership of federal and state governments established to provide coverage for health services for eligible persons. Florida's program is administered by the AHCA and financed through state and federal funds.¹

¹ Section 20.42, F.S.

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs. The state plan establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.

In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives states the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards. The AHCA may seek an amendment to the state plan as necessary to comply with federal or state laws or to implement program changes.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program.² The SMMC program has three components, the Managed Medical Assistance (MMA) program, the Long-term Care program, and dental plans. Florida's SMMC offers a health care package covering acute, preventive, behavioral health, prescribed drugs, long-term care, and dental services.³ The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S.

The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in 2014 and was re-procured for a period beginning December 2018 and ending in 2023.⁴

Coverage of Prescribed Drugs

Section 409.91195, F.S., establishes the Pharmaceutical and Therapeutics Committee within the AHCA and tasks it with developing a Florida Medicaid Preferred Drug List (PDL). The Governor appoints the eleven committee members, including five pharmacists, five physicians, and one consumer representative.⁵ The committee must meet quarterly and must review all drug classes included in the PDL at least every 12 months.⁶ The committee may recommend additions to and deletions from the PDL, such that the PDL provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.⁷

The committee considers the amount of rebates drug manufacturers are offering if their drug is placed on the PDL.⁸ These state-negotiated supplemental rebates, along with federally negotiated rebates, can reduce the per-prescription cost of a brand name drug to below the cost of its generic

² Agency for Health Care Administration, *Senate Bill 534 Analysis* (Nov. 11, 2021) (on file with Senate Committee on Health Policy).

³ *Id.*

⁴ Agency for Health Care Administration, *Statewide Medicaid Managed Care: Overview*, available at https://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/SMMC_Overview_12042018.pdf (last visited Feb. 20, 2023).

⁵ Section 409.91195(1), F.S.

⁶ Section 409.91195(3), F.S.

⁷ Section 409.91195(4), F.S.

⁸ Section 409.91195(7), F.S.

equivalent.⁹ Florida currently collects over \$2 billion per year in federal and supplemental rebates for drugs dispensed to Medicaid recipients.¹⁰ These funds are used to offset the cost of Medicaid services.¹¹

Medicaid managed care plans are required by the AHCA to provide all prescription drugs listed on the AHCA's PDL.¹² Because of this, the managed care plans have not implemented their own plan-specific formularies or PDLs. Medicaid managed care plans are required to provide a link to the AHCA's PDL on their websites.¹³ Florida Medicaid covers all Food and Drug Administration (FDA) approved prescription medications.¹⁴ Those not included on the PDL must be prior-approved by Medicaid or the health plans.¹⁵

The AHCA also manages the federally required Florida Medicaid Drug Utilization Review Board, which meets quarterly and develops and reviews clinical prior authorization criteria, including step-therapy protocols, for certain drugs that are not on the AHCA's Medicaid PDL.¹⁶

Prescribed Drug Prior Authorization Requirements, Step-Therapy Protocols

Prior authorization means a process by which a health care provider must qualify for payment coverage by obtaining advance approval from an insurer before a specific service is delivered to the patient.¹⁷ Within the Florida Medicaid program, only care, goods, and services that are medically necessary will obtain prior authorization. The AHCA must respond to prior authorization requests for prescribed drugs within 24 hours of receipt of the request.¹⁸ Medicaid managed care plans are contractually required to respond to prior authorization requests for prescribed drugs within 24 hours of receipt of the request.

Section 409.912(5)(a)14., F.S. requires the AHCA to implement a step-therapy¹⁹ prior authorization process for prescribed drugs excluded from the PDL. The recipient must try the prescribed drug on the PDL within the 12 months before a non-PDL drug is approved. However, a non-PDL drug may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides additional written medical documentation that the non-PDL product is medically necessary because:

- There is not a drug on the PDL to treat the disease or medical condition which is an acceptable clinical alternative;
- The alternative drugs have been ineffective in the treatment of the recipient's disease;

⁹ *Supra* note 2.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ Section 409.967(2)(c)2, F.S.

¹⁴ *Supra* note 2.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Riley, Hannah, Gistia Healthcare, *Making Sense of Prior Authorization, What is it?* (Apr. 21, 2020) available at <https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20is%20it%20-Gistia%20Healthcare.pdf> (last visited Feb. 20, 2023).

¹⁸ Section 409.912(5)(a)1.a., F.S.

¹⁹ Step therapy means trying less expensive options before "stepping up" to drugs that cost more. Blue Cross Blue Shield Blue Care Network of Michigan, *How does step therapy work?*, available at <https://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/pharmacy/what-is-step-therapy.html> (last visited Feb. 20, 2023).

- The drug product or medication of a similar drug class is prescribed for the treatment of schizophrenia or schizotypal or delusional disorders; prior authorization has been granted previously for the prescribed drug; and the medication was dispensed to the patient during the previous 12 months; or
- Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses has been ineffective.

The AHCA must work with the physician to determine the best alternative for the recipient.²⁰

Regardless of whether a drug is listed on the PDL, a Medicaid managed care plan's prior authorization criteria and protocols related to prescribed drugs cannot be more restrictive than the criteria established by the AHCA for Fee-for-Service Delivery System prior authorizations.²¹ Medicaid managed care plans must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers and must provide timely responses to providers.²²

Coverage of Prescription Drugs for Serious Mental Illnesses

Drugs treating serious mental illness accounted for over \$131 million in paid claims in the Medicaid program during 2022. Antidepressants compose one of the largest drug classes and are responsible for over \$30 million in paid claims per year.²³

Tricyclic Antidepressants

As of March 2022, 99.9 percent of the paid claims in this class were for preferred drugs. The net cost of non-preferred drugs can be 10 times greater than the net cost of preferred drugs with the same mechanism of action.²⁴

Selective Serotonin Reuptake Inhibitors (SSRI) Antidepressants:

As of June 2022, 99.3 percent of the paid claims in this class were for preferred drugs. The cost of non-preferred drugs can be 22 times greater than the cost of preferred drugs within the same therapeutic class.²⁵

Other Antidepressants

As of June 2022, 99.9 percent of the paid claims in this class were for preferred drugs. This class contains oral and injectable antidepressant drugs. The cost of oral non-preferred drugs can be 17 times greater than the cost of preferred drugs within the review class, which includes all oral antidepressants that are not tricyclic or SSRIs.²⁶

²⁰ Section 409.912(5)(a)14., F.S.

²¹ *Supra* note 2.

²² Section 409.967(2)(c)2, F.S.

²³ Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis: SB 112*, Feb. 17, 2023, on file with the Senate Committee on Health Policy.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

Antipsychotics

As of September 2022, 98.3 percent of the paid claims in this class were for preferred drugs. PDL compliance results in significant savings annually in the antipsychotic class.²⁷

The Medicaid PDL includes numerous generic and brand name drugs for the treatment of serious mental illness.²⁸ If a drug is not on the PDL, the prescriber must obtain prior authorization before dispensing the medication. AHCA and Medicaid managed care plans are required to respond to prior authorization requests within 24 hours of receipt. Prior authorization requests for mental health medications are reviewed using the Psychotherapeutic Medication Guidelines established by the University of South Florida.²⁹

The AHCA maintains prior authorization criteria and automated edits.³⁰

Prescription Drugs Used in the Treatment of Schizophrenia for Medicaid Recipients

In the 2022 Regular Legislative Session, the Legislature enacted SB 534,³¹ which amended s. 409.912, F.S., to create an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product if the prescribing physician provides the AHCA with written medical or clinical documentation that the product is medically necessary. Under SB 534, medical necessity is created when the drug product or a medication of a similar drug class is being prescribed for the treatment of schizophrenia or schizotypal or delusional disorders, prior authorization has previously been granted to the patient for the prescribed drug, and the medication had been dispensed to the patient during the previous 12 months.

After the step therapy requirement was mitigated by the enactment of SB 534 in 2022 for the schizophrenia-related medications, the PDL compliance decreased 0.1 percent in the antipsychotic class. This decrease in compliance results in a reduction in collection of manufacturer rebates that offset the cost of Medicaid drug spending.³²

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 409.901, F.S., to create a definition of the term “serious mental illness” pertaining to the Medicaid program. The bill defines that term to mean any of the following psychiatric disorders as defined by the American Psychiatric Association in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*:³³

²⁷ *Id.*

²⁸ See the PDL at https://ahca.myflorida.com/medicaid/Prescribed_Drug/preferred_drug.shtml (last visited Feb. 20, 2023).

²⁹ See the guidelines at <https://floridabhcenter.org/> (last visited Feb. 20, 2023).

³⁰ See the criteria at https://ahca.myflorida.com/medicaid/Prescribed_Drug/drug_criteria.shtml (last visited Feb. 20, 2023).

³¹ See Chapter 2022-27, Laws of Florida.

³² *Supra*, note 23.

³³ According to the American Psychiatric Association, *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR)*, not the original Fifth Edition, is the Association’s latest version of the manual. The Association indicates that “*DSM-5-TR* features the most current text updates based on scientific literature with contributions from more than 200 subject matter experts. The revised version includes a new diagnosis (prolonged grief disorder), clarifying modifications to the criteria sets for more than 70 disorders, addition of *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)* symptom codes for suicidal behavior and nonsuicidal self-injury, and updates to descriptive text for most disorders based on extensive review of the literature. In addition, *DSM-5-TR* includes a

- Bipolar disorders, including hypomanic, manic, depressive, and mixed-feature episodes.
- Depression in childhood or adolescence.
- Major depressive disorders, including single and recurrent depressive episodes.
- Obsessive-compulsive disorders.
- Paranoid personality disorder or other psychotic disorders.
- Schizoaffective disorders, including bipolar or depressive symptoms.
- Schizophrenia.

Section 2 of the bill amends s. 409.912(5)(a), F.S., to create an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product that is prescribed for the treatment of a serious mental illness or a medication of a similar drug class if prior authorization was previously granted for the prescribed drug and the medication was dispensed to the patient during the previous 12 months. The bill requires that in cases involving drugs for the treatment of a serious mental illness, the exception must be approved, as opposed to the AHCA being authorized to approve the exception as in current law.

Section 3 of the bill amends s. 409.910(20)(a), F.S., to make a conforming change.

Section 4 of the bill directs the AHCA to include the bill's rate impact on new managed care plan payment rates within Statewide Medicaid Managed Care that take effect October 1, 2023.

Section 5 provides an effective date of October 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

comprehensive review of the impact of racism and discrimination on the diagnosis and manifestations of mental disorders. The manual will help clinicians and researchers define and classify mental disorders, which can improve diagnoses, treatment, and research.” See <https://www.psychiatry.org/psychiatrists/practice/dsm> (last visited Feb. 21, 2023).

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The AHCA reports that:³⁴

- CS/SB 112 will have an operational impact on both the Florida Medicaid fee-for-service delivery system and Statewide Medicaid Managed Care because there will need to be changes made to all coding related to drugs used to treat serious mental illness.
- In addition to the operational impact, the potential fiscal impact will be significant. Fiscally, the bill could have adverse impact on the state Medicaid budget. The Medicaid PDL includes many effective generic and brand-name medications with robust federal rebates and additional supplemental rebates offered by drug manufacturers, resulting in reduced cost to Medicaid. If numerous prescribing physicians elect to prescribe drugs that are not on the PDL under the bill, it may lead to an increase in net drug cost in therapeutic classes related to serious mental illness.
- After the enactment of SB 534 on July 1, 2022, the Medicaid program observed a relative decrease in the amount of rebates collected for the treatment of schizophrenia. A substantial decrease in rebates relative to the large number of drugs used to treat serious mental illness could be expected if CS/SB 112 takes effect as written. Antipsychotics alone are projected to result in the collection of over \$13 million in rebates in the current fiscal year, with a total spend of more than \$70 million. The loss of rebates for a class this size could increase the overall cost of pharmacy spending in Florida Medicaid.

In terms of numbers, the AHCA indicates that the fiscal impact of the bill is indeterminate, with the caveat that, according to the fiscal year 2020-2021 data, Florida Medicaid spent over \$117 million on medications for the treatment of serious mental illness. If numerous prescribing physicians elect to prescribe drugs that are not on the PDL, and the bill's provisions are applied, it may lead to an increase in drug cost in therapeutic classes related to serious mental illness due to the loss of the AHCA's bargaining power in terms of negotiating rebates. Every one-percent loss in the rate of PDL compliance could generate a \$1.1 million increase in Medicaid expenses. The extent of such noncompliance under the bill is unknown.³⁵

³⁴ *Supra*, note 23.

³⁵ *Id.*

The bill could also mitigate costs to the Medicaid program or other state expenditures in indirect ways. For example, if Medicaid recipients needing certain drugs for serious mental illness experience a delay in access to those drugs due to the step-therapy protocol, such delay could lead to the need for other costly treatments, such as the costs of involuntary evaluation during a mental health crisis.³⁶ Such impact is also indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill's list of psychiatric disorders as defined by the American Psychiatric Association in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, includes "paranoid personality disorder or other psychotic disorders." The *DSM-5* categorizes the following disorders under Schizophrenia and "other psychotic disorders":³⁷

- Schizotypal (Personality) Disorder;
- Delusional Disorder;
- Brief Psychotic Disorder;
- Schizophreniform Disorder;
- Schizophrenia;
- Schizoaffective Disorder;
- Substance/Medication-Induced Psychotic Disorder;
- Psychotic Disorder Due to Another Medical Condition;
- Catatonia;
- Other Specified Schizophrenia Spectrum and Other Psychotic Disorder; and
- Unspecified Schizophrenia Spectrum and Other Psychotic Disorder.

With the exception of schizophrenia and schizoaffective disorder, the bill includes these disorders by reference to the *DSM-5* as "other psychotic disorders" but does not list them by name. The *DSM-5* might classify other disorders as psychotic disorders that do not appear in this list.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.901, 409.912, and 409.910.

³⁶ See s. 394.463, F.S., within the Florida Mental Health Act.

³⁷ Wiregrass Georgia Technical College, *DSM-5: Schizophrenia Spectrum and Other Psychotic Disorders*, available at: <https://wiregrass.libguides.com/c.php?g=1044445&p=7583272> (last visited Feb. 21, 2023).

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 20, 2023

The CS changes the effective date from July 1, to October 1, 2023, and directs AHCA to consider the bill's impact when setting capitation rates for Medicaid managed care plans for the upcoming contract year that also begins October 1, 2023.

- B. **Amendments:**

None.