

**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.)

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

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BILL: SB 534

INTRODUCER: Senator Harrell

SUBJECT: Prescription Drugs Used in the Treatment of Schizophrenia for Medicaid Recipients

DATE: December 1, 2021

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	<b>Favorable</b>
2.			AHS	
3.			AP	

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**I. Summary:**

SB 534 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 schizophrenia or schizotypal or delusional disorders 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 poses an indeterminate fiscal impact on the Florida Medicaid Program.

The bill provides an effective date of July 1, 2022.

**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 Agency for Health Care Administration (AHCA) and financed through state and federal funds.<sup>1</sup>

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.

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<sup>1</sup> Section 20.42, F.S.

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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

### ***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.<sup>5</sup> The committee must meet quarterly and must review all drug classes included in the PDL at least every 12 months.<sup>6</sup> 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.<sup>7</sup>

The committee considers the amount of rebates drug manufacturers are offering if their drug is placed on the PDL.<sup>8</sup> 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 equivalent.<sup>9</sup> Florida currently collects over \$2 billion per year in federal and supplemental rebates for drugs dispensed to Medicaid recipients.<sup>10</sup> These funds are used to offset the cost of Medicaid services.<sup>11</sup>

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

<sup>3</sup> *Id.*

<sup>4</sup> 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](https://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/SMMC_Overview_12042018.pdf) (last visited Nov. 30, 2021).

<sup>5</sup> Section 409.91195(1), F.S.

<sup>6</sup> Section 409.91195(3), F.S.

<sup>7</sup> Section 409.91195(4), F.S.

<sup>8</sup> Section 409.91195(7), F.S.

<sup>9</sup> *Supra* note 2.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

Medicaid managed care plans are required to provide all prescription drugs listed on the AHCA's PDL.<sup>12</sup> 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.<sup>13</sup> Florida Medicaid covers all Food and Drug Administration (FDA) approved prescription medications.<sup>14</sup> Those not included on the PDL must be prior-approved by Medicaid or the health plans.<sup>15</sup>

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.<sup>16</sup>

### ***Medical Necessity***

Federal law specifies that state Medicaid programs may not cover services that are not reasonable and (medically) necessary.<sup>17</sup> Each state has adopted its own definition of "medical necessity."<sup>18</sup> Section 409.913(1)(d), F.S., specifies that the AHCA is the final arbiter of medical necessity for purposes of medical reimbursement. Further, that paragraph requires determinations of medical necessity to be made by a licensed physician employed by or under contract with the AHCA (except for behavior analysis services, which may be determined by either a licensed physician or a doctoral-level board-certified behavior analyst), based upon information available at the time the goods or services are requested.

Pursuant to Rule 59G-1.010 of the Florida Administrative Code, care, goods, and services are medically necessary if they are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
- Consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- Reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- Furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

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<sup>12</sup> *Id.*

<sup>13</sup> Section 409.967(2)(c)2, F.S.

<sup>14</sup> *Supra* note 2.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> 42 U.S.C. s. 1395y.

<sup>18</sup> Dickey, Elizabeth, NOLO, Getting Approval for Medicaid Services: Medical Necessity *available at* <https://www.nolo.com/legal-encyclopedia/getting-approval-medicaid-services-medical-necessity.html> (last visited Nov. 30, 2021).

### ***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.<sup>19</sup> 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.<sup>20</sup> 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-therapy<sup>21</sup> 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; 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.<sup>22</sup>

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.<sup>23</sup> 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.<sup>24</sup>

### ***Coverage of Prescription Drugs for Schizophrenia, Schizotypal, and Delusion Disorders***

The PDL can be found on the AHCA's website.<sup>25</sup> The AHCA reports that the list includes numerous generic and brand name drugs for the treatment of schizophrenia, schizotypal or delusional disorders.<sup>26</sup> If the drug is not on the PDL, the prescriber must obtain prior authorization before dispensing the medication. Prior authorization requests are reviewed using

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<sup>19</sup> Riley, Hannah, Gistia Healthcare, *Making Sense of Prior Authorization, What is it?* (Apr. 21, 2020) available at <https://www.gistia.com/insights/what-is-prior-authorization> (last visited Nov. 30, 2021).

<sup>20</sup> Section 409.912(5)(a)1.a., F.S.

<sup>21</sup> 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 Nov. 30, 2021).

<sup>22</sup> Section 409.912(5)(a)14., F.S.

<sup>23</sup> *Supra* note 2.

<sup>24</sup> Section 409.967(2)(c)2, F.S.

<sup>25</sup> Agency for Health Care Administration, Florida Medicaid Preferred Drug List (PDL) available at [https://ahca.myflorida.com/medicaid/prescribed\\_drug/pharm\\_thera/fmpdl.shtml](https://ahca.myflorida.com/medicaid/prescribed_drug/pharm_thera/fmpdl.shtml) (last visited Nov. 30, 2021).

<sup>26</sup> *Supra* note 2.

the guidelines established by the University of South Florida for mental health medications.<sup>27</sup> Prior authorization criteria and automated edits can be found on the AHCA's website.<sup>28</sup>

### **Schizophrenia, Schizotypal, and Delusional Disorders**

It was estimated that in 2017, approximately 184,607 adults residing in Florida had schizophrenia. Of that number, approximately 73,843 went untreated.<sup>29</sup>

Schizophrenia is a serious mental disorder that causes people to interpret reality abnormally. Schizophrenia may result in some combination of hallucinations, delusions, and extremely disordered thinking and behavior that impairs daily functioning, and can be disabling.<sup>30</sup> People with schizophrenia require lifelong treatment. Treatments may include: biofeedback and stress management, electroconvulsive therapy, psychotherapy, psychopharmacology (the use of medications), and repetitive transcranial magnetic stimulation.<sup>31</sup> Common medications include one, or a combination of, antidepressants, mood stabilizers, anti-psychotic drugs, anti-anxiety medicines, and stimulants.<sup>32</sup> These treatments are also used for patients with schizotypal personality disorders and delusional disorders.

Schizotypal Personality Disorder can easily be confused with schizophrenia. While people with schizotypal personality disorder may experience brief psychotic episodes with delusions or hallucinations, the episodes are not as frequent, prolonged, or intense as in schizophrenia.<sup>33</sup> Furthermore, people with schizotypal personality disorder usually can be made aware of the difference between their distorted ideas and reality. Those with schizophrenia generally cannot be swayed from their delusions.<sup>34</sup>

Similarly, Delusional Disorder is distinguished from schizophrenia by the presence of a delusion or delusions persisting for at least a month without any of the other symptoms of psychosis (for example, hallucinations, disorganized speech, or disorganized behavior).<sup>35</sup>

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<sup>27</sup> *Supra* note 2. The guidelines can be found at <https://floridabhcenter.org/> (last visited Nov. 30, 2021). These guidelines are included on the criteria for antipsychotic medications.

<sup>28</sup> Agency for Health Care Administration, Drug Criteria, *available at* [https://ahca.myflorida.com/medicaid/prescribed\\_drug/drug\\_criteria.shtml](https://ahca.myflorida.com/medicaid/prescribed_drug/drug_criteria.shtml) (last visited Nov. 30, 2021).

<sup>29</sup> Treatment Advocacy Center, Florida, *available at* <https://www.treatmentadvocacycenter.org/browse-by-state/florida> (last visited Nov. 30, 2021).

<sup>30</sup> Mayo Clinic, Schizophrenia, *available at* <https://www.mayoclinic.org/diseases-conditions/schizophrenia/symptoms-causes/syc-20354443> (last visited Nov. 30, 2021).

<sup>31</sup> University of Miami Health System, Schizophrenia, *available at* <https://umiamihealth.org/en/treatments-and-services/psychiatry/schizophrenia> (last visited Nov. 30, 2021).

<sup>32</sup> *Id.*

<sup>33</sup> Mayo Clinic, Schizotypal Personality Disorder, *available at* <https://www.mayoclinic.org/diseases-conditions/schizotypal-personality-disorder/symptoms-causes/syc-20353919> (last visited Nov. 30, 2021).

<sup>34</sup> *Id.*

<sup>35</sup> Carol Tamminga, MD, Delusional Disorder, *Merk Manual* (May 2020), *available at* <https://www.merckmanuals.com/home/mental-health-disorders/schizophrenia-and-related-disorders/delusional-disorder> (last visited Nov. 30, 2021).

### III. Effect of Proposed Changes:

**Section 1** of the bill amends s. 409.912(5)(a)14., 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 schizophrenia or schizotypal or delusional disorders 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.

In practice, the pharmacy benefit manager for the Florida Medicaid Fee-for-Service delivery system would review the exception request on behalf of the AHCA. Managed care plans would process their own exceptions. Providers may transmit written medical or clinical documentation by facsimile or submit their requests through the electronic prior authorization system (ePA).<sup>36</sup>

**Section 2** of the bill provides an effective date of July 1, 2022.

### 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.

### V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

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<sup>36</sup> *Supra* note 2.

**C. Government Sector Impact:**

The AHCA reports that the bill poses an indeterminate fiscal impact on the Florida Medicaid Program. The PDL includes many generic medications with robust federal rebates and often additional supplemental rebates offered by drug manufacturers, resulting in a reduced cost to Medicaid. If numerous prescribing physicians prescribe higher cost, non-PDL drugs through the exception created in this bill, it may lead to a cost increase in therapeutic classes related to schizophrenia treatment.<sup>37</sup>

However, if the bill results in more expeditious and effective pharmaceutical care provided to Medicaid patients with the targeted disorders, the program could experience savings due to reductions in the need for other types of expenses, such as, for example, expenses associated with inpatient hospital care. Such potential effect is indeterminate.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the section 409.912 of the Florida Statutes.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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<sup>37</sup> *Supra* note 2.