

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 183 Medicaid Step-Therapy Protocols for Drugs for Serious Mental Illness Treatments

**SPONSOR(S):** Healthcare Regulation Subcommittee, Gonzalez Pittman

**TIED BILLS:** IDEN./SIM. BILLS: SB 112

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	17 Y, 0 N, As CS	Guzzo	McElroy
2) Health Care Appropriations Subcommittee	14 Y, 0 N	Smith	Clark
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

Mental illness refers to a wide range of mental health conditions — disorders that affect mood, thinking and behavior, including depression, anxiety disorders, schizophrenia, eating disorders and addictive behaviors. Many people have mental health concerns from time to time, but a mental health concern becomes a mental illness when ongoing signs and symptoms cause frequent stress and affect the ability to function.

A person with a serious mental illness (SMI) is someone over the age of 18 who has, or had within the past year, a diagnosable mental, behavioral, or emotional disorder that causes serious functional impairment that substantially interferes with or limits one or more major life activities. SMI is a small subset of the 300 mental illnesses listed in the Diagnostic and Statistical Manual of Mental Disorders, and includes disorders such as bipolar disorder, major depressive disorder, schizophrenia, and schizoaffective disorder.

Both commercial and government sector health coverage apply utilization management techniques to reduce costs, maximize volume pricing arrangements, and prevent catastrophic medical events. Step therapy, is one such technique, commonly used with prescription drug benefits. Step therapy policies require enrollees to first try a preferred drug or service before obtaining an alternate drug or service for a particular medical condition. Step therapy is commonly used in conjunction with prior authorization policies, which require providers to obtain approval from an insurer before a patient may receive specified prescription drugs under the plan. Step therapy policies require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition.

CS/HB 183 requires the Medicaid program to approve a drug product for the treatment of a SMI without meeting the step-therapy and prior authorization criteria if the prescribing physician documents to the Agency for Health Care Administration (AHCA) that the drug is medically necessary because:

- There is no drug on the Florida Medicaid Preferred Drug List (PDL) to treat the SMI which is an acceptable clinical alternative;
- The alternatives have been ineffective in the patient's SMI treatment;
- The drug product or medication of a similar drug class is prescribed for the treatment of a SMI; 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 historical 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 bill directs the AHCA to include the impact of the bill on Medicaid managed medical assistance and long-term care managed care program rates effective on October 1, 2023.

The bill will have an indeterminate, but likely significant negative fiscal impact on the Medicaid program, and no fiscal impact on local government. See Fiscal Comments.

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

**This document does not reflect the intent or official position of the bill sponsor or House of Representatives .**

**STORAGE NAME:** h0183c.HCA

**DATE:** 4/12/2023

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

#### Serious Mental Illness

Mental illness refers to a wide range of mental health conditions — disorders that affect mood, thinking and behavior, including depression, anxiety disorders, schizophrenia, eating disorders and addictive behaviors.<sup>1</sup> Many people have mental health concerns from time to time, but a mental health concern becomes a mental illness when ongoing signs and symptoms cause frequent stress and affect the ability to function.<sup>2</sup>

Signs and symptoms of mental illness can vary, depending on the disorder, circumstances and other factors. Mental illness symptoms can affect emotions, thoughts and behaviors. Examples of signs and symptoms include:

- Feeling sad or down
- Confused thinking or reduced ability to concentrate
- Excessive fears or worries, or extreme feelings of guilt
- Extreme mood changes of highs and lows
- Withdrawal from friends and activities
- Significant tiredness, low energy or problems sleeping
- Detachment from reality (delusions), paranoia or hallucinations
- Inability to cope with daily problems or stress
- Trouble understanding and relating to situations and to people
- Problems with alcohol or drug use
- Major changes in eating habits
- Sex drive changes
- Excessive anger, hostility or violence
- Suicidal thinking<sup>3</sup>

Sometimes symptoms of a mental health disorder appear as physical problems, such as stomach pain, back pain, headaches, or other unexplained aches and pains.<sup>4</sup>

A person with a serious mental illness (SMI) is someone over the age of 18 who has, or had within the past year, a diagnosable mental, behavioral, or emotional disorder that causes serious functional impairment that substantially interferes with or limits one or more major life activities.<sup>5</sup> SMI is a small subset of the 300 mental illnesses listed in the Diagnostic and Statistical Manual of Mental Disorders, and includes disorders such as bipolar disorder, major depressive disorder, schizophrenia, and schizoaffective disorder.<sup>6</sup>

#### Florida Medicaid

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<sup>1</sup> Mayo Clinic, Patient Care and Health Information, *Diseases and Conditions— Mental Illness*, available at <https://www.mayoclinic.org/diseases-conditions/mental-illness/symptoms-causes/syc-20374968> (last viewed on April 10, 2023).

<sup>2</sup> *Id.*

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

<sup>4</sup> *Id.*

<sup>5</sup> American Psychiatric Association and Substance Abuse and Mental Health Services Administration, SMIAdviser, *What Is Serious Mental Illness?*, available at <https://smiadviser.org/about/serious-mental-illness> (last viewed on April 10, 2023).

<sup>6</sup> *Id.*

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds.

The structure of each state's Medicaid program varies, but what states must pay for is largely determined by the federal government, as a condition of receiving federal funds.<sup>7</sup> The federal government sets the minimum mandatory populations to be included in every program, and the minimum mandatory benefits to be covered. These mandatory benefits include physician services, hospital services, home health services, and family planning, but do not include prescription drugs.<sup>8</sup> States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drug coverage.<sup>9</sup>

The Florida Medicaid program covers approximately 5.7 million low-income individuals in Florida.<sup>10</sup> Medicaid is the largest single program in the state, representing more than 44 percent of the total Fiscal Year 2022-2023 General Appropriations Act.<sup>11</sup> Florida's program is the 4th largest in the nation by enrollment and, for FY 2020-2021, the program is the 4th largest in terms of expenditures.<sup>12</sup>

Florida delivers medical assistance to most Medicaid recipients - approximately 78% - using a comprehensive managed care model.<sup>13</sup> While current law requires provision of all Medicaid covered services for these recipients through this managed care model,<sup>14</sup> AHCA retains control over prescription drug benefits for both the managed care and the remaining fee-for-service populations.

#### Medicaid Prescribed Drug Benefits – Cost Control

Federal law requires state Medicaid programs to cover every drug for which the federal Department of Health and Human Services (HHS) has negotiated a manufacturer rebate.<sup>15</sup> Florida law requires AHCA to have a spending control program for this benefit, including a state-negotiated supplemental rebate, which is in addition to the federal rebate.<sup>16</sup> AHCA contracts with a pharmacy benefit manager to negotiate those rebates. Revenues generated from the rebates are reinvested in the Medicaid program.

Part of the spending control program is a Medicaid Preferred Drug List (PDL). The PDL is a list of drugs which are the most cost-effective options in each therapeutic class.<sup>17</sup> AHCA establishes the PDL based on the clinical efficacy and safety of the drug, as well as the price of the drug and the price of competing products, taking into account the federal and state rebates.<sup>18</sup> In developing the PDL, AHCA must consider the recommendations of the Medicaid Pharmacy and Therapeutics Committee, a committee of clinicians which reviews drugs for clinical efficacy, safety and cost-effectiveness.<sup>19</sup>

Another component of the spending control program is prior authorization. Current law allows AHCA to condition reimbursement on prior authorization; that is, the prescriber or dispenser must obtain AHCA

<sup>7</sup> Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725).

<sup>8</sup> S. 409.905, F.S.

<sup>9</sup> S. 409.906, F.S.

<sup>10</sup> Agency for Health Care Administration, *Florida Statewide Medicaid Monthly Enrollment Report*, Feb. 2023, available at [https://ahca.myflorida.com/medicaid/Finance/data\\_analytics/enrollment\\_report/index.shtml](https://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml) (last viewed on April 10, 2023).

<sup>11</sup> Ch. 2022-156, Laws of Fla. See also *Fiscal Analysis in Brief: 2022 Legislative Session*, available at <http://edr.state.fl.us/content/revenues/reports/fiscal-analysis-in-brief/FiscalAnalysisinBrief2022.pdf> (last viewed on April 10, 2023).

<sup>12</sup> The Henry J. Kaiser Family Foundation, *State Health Facts, Total Medicaid Spending FY2021 and Total Monthly Medicaid and CHIP Enrollment Nov. 2022*, available at <http://kff.org/statedata/> (last viewed on April 10, 2023).

<sup>13</sup> S. 409.964, F.S.

<sup>14</sup> S. 409.964, F.S.

<sup>15</sup> Title 42 U.S.C. § 1396r-8. State Medicaid programs are authorized to cover non-rebated drugs with HHS approval, under certain circumstances.

<sup>16</sup> S. 409.912(5)(a), F.S.

<sup>17</sup> S. 409.912(5)(a), F.S.; Agency for Health Care Administration, *Florida Medicaid Preferred Drug List*, March 8, 2023, 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 viewed on April 10, 2023).

<sup>18</sup> SS. 409.912(5)(a)7., 409.91195(7), F.S.

<sup>19</sup> S. 409.91195, F.S. The P&T Committee is comprised of 11 gubernatorial appointees, including four physicians, five pharmacists and a consumer member. It must meet at least quarterly, and must review all drug classes every 12 months. Meetings are open to the public, and the committee is required to receive public testimony from interested parties; however, portions of meetings during which rebates and other trade secrets are discussed are closed, pursuant to s. 409.91196, F.S., and 42 U.S.C. 1396r-8(b)(3)(D).

(or managed care plan) approval prior to dispensing, or Medicaid will not pay for the drug.<sup>20</sup> AHCA may require prior authorization:<sup>21</sup>

- For an indication not approved in labeling;
- To comply with clinical guidelines; or
- If the product has the potential for overuse, misuse, or abuse.

In the prior authorization process, the prescriber may be required to provide the rationale and supporting medical evidence for the use of a drug.<sup>22</sup> For prior authorized PDL drugs, the prior authorization system must guarantee a response within 24 hours, and cover a 72-hour supply of the drug if that time is exceeded.<sup>23</sup>

### Prescribed Drug Step Therapy

Both commercial and government sector health coverage apply utilization management techniques to reduce costs, maximize volume pricing arrangements, and prevent catastrophic medical events. Step therapy, is one such technique, commonly used with prescription drug benefits. Step therapy policies require enrollees to first try a preferred drug or service before obtaining an alternate drug or service for a particular medical condition.

Step therapy is commonly used in conjunction with prior authorization policies, which require providers to obtain approval from an insurer before a patient may receive specified prescription drugs under the plan. For example, most insurers have a formulary or preferred drug list, which is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. Prior authorization would limit an insured's ability to obtain another drug within the therapeutic class that is not part of the PDL without the insurer authorizing that drug.

Step therapy policies require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe the most cost-effective drug, Drug A, first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. Step therapy is also known as "fail-first", as the insurer restricts coverage of expensive therapies unless patients have already failed treatment with a lower-cost alternative.

Step therapy and prior authorization are enforcement mechanisms for an insurer's preferred drug list or formulary. They ensure that actual transaction volumes and manufacturer rebate levels align with the actuarial assumptions that generated the price of the insurance coverage, while accommodating clinically justified exceptions.

Researchers report that there is mixed evidence on the impact of step therapy policies.<sup>24</sup> A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.<sup>25</sup> Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,<sup>26</sup> while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.<sup>27</sup>

### *Commercial Insurance Step Therapy Regulation*

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<sup>20</sup> S. 409.91195(5), F.S.

<sup>21</sup> S. 409.912(5)(a)12., F.S.

<sup>22</sup> *Id.*

<sup>23</sup> S. 409.912(5)(a), F.S.

<sup>24</sup> Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, Health Affairs 33, No.10 (2014):1779-1785, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0516> (last viewed on April 10, 2023).

<sup>25</sup> Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, Journal of Managed Care Pharmacy 17, no. 2 (2011) 143-55, <http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143> (last viewed on April 10, 2023).

<sup>26</sup> *Supra* note 24, at pg. 1780.

<sup>27</sup> *Id.*

Currently, Florida law limits the use of step therapy in commercial health insurance. Insurers and health maintenance organizations (HMOs) may not require a step therapy protocol for a covered individual if they:

- Were previously approved to receive a specific drug through completion of a step therapy protocol by another health insurance plan; and,
- Can provide documentation from the other health insurance plan indicating that the specific drug was paid for on the individual's behalf within the past 90 days.<sup>28</sup>

#### *Medicaid Step Therapy Requirements*

While Florida Medicaid covers all federally-rebated drugs, the use of drugs which are not on the PDL is subject to additional scrutiny. Current law requires reimbursement for non-PDL drugs to be subject to a step-therapy prior authorization process; specifically, PDL-listed drugs must have been used at some point within the last 12 months before a non-listed drug can be used.<sup>29</sup> The step-therapy policy does not apply if the prescriber provides medical or clinical documentation showing:<sup>30</sup>

- There is no drug on the PDL to treat the disease or medical condition which is an acceptable clinical alternative;
- The alternatives have been ineffective in the treatment of the beneficiary'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.

#### *Medicaid Step Therapy Exception for Drugs for Schizophrenia, Schizotypal, or Delusion Disorders*

The Medicaid PDL includes numerous generic and brand name drugs for the treatment of serious mental illness, including schizophrenia, schizotypal or delusional disorders. If the drug is not on the PDL, the prescriber must obtain prior authorization before dispensing the medication.

When conducting prior authorization for mental health medications, AHCA uses guidelines developed by the University of South Florida<sup>31</sup>, and includes those guidelines with the prior authorization criteria it publishes online for prescribers.<sup>32</sup>

In 2022, the Legislature added an exception to the requirement to use step therapy for non-PDL drugs for medications used to treat schizophrenia, schizotypal or delusional disorders. The exception applies if the prescriber provides clinical documentation that the product is medically necessary because the patient had recently used it within the Medicaid program; that is:

- Prior authorization was granted previously for the same drug; and
- The medication was dispensed to the patient in the last 12 months.

#### **Effect of Proposed Bill**

CS/HB 183 requires the Medicaid program to approve a drug product for the treatment of a SMI without meeting the step-therapy and prior authorization criteria if the prescribing physician documents to AHCA that the drug is medical necessary because:

- There is no drug on the PDL to treat the SMI which is an acceptable clinical alternative;
- The alternatives have been ineffective in the patient's SMI treatment;

<sup>28</sup> Ss. 627.42393 and 641.31(46), F.S.

<sup>29</sup> S. 409.912(5)(a)14., F.S.

<sup>30</sup> *Id.*

<sup>31</sup> University of South Florida, Florida Center for Behavioral Health Improvements and Solutions, *Psychotherapeutic Medication Guidelines 2019-2020*, available at [Florida Center for Behavioral Health Improvements and Solutions \(floridabhcenter.org\)](https://www.floridabhcenter.org) (last viewed on April 10, 2023).

<sup>32</sup> Agency for Health Care Administration, *Drug Criteria*, available at [Drug Criteria \(myflorida.com\)](https://www.myflorida.com) (last viewed on April 10, 2023).

- The drug product or medication of a similar drug class is prescribed for the treatment of a SMI; 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 historical 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.

For the purposes of the bill, SMI means any of the following psychiatric disorders, defined by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition:

- 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

The bill directs AHCA to include the rate impact of the bill on program rates for Medicaid managed medical assistance and long-term care managed care, effective October 1, 2023.

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

## B. SECTION DIRECTORY:

**Section 1:** Amends s. 409.901, F.S., relating to definitions; ss. 409.901-409.920.

**Section 2:** Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.

**Section 3:** Amends s. 409.910, F.S., relating to responsibility for payments on behalf of Medicaid-eligible persons when other parties are liable.

**Section 4:** Creates an unnumbered section of law directing AHCA to include the impact of removing SMI drugs from step-therapy protocols on program rates for Medicaid managed medical assistance and long-term care managed care, effective October 1, 2023.

**Section 5:** Provides an effective date of October 1, 2023.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

The bill will have an indeterminate, but likely significant negative fiscal impact to revenues from drug rebates. The bill limits on use of step therapy for drugs for serious mental illness will result in lower drug manufacturer rebates revenues to AHCA, due to reduced rebate negotiation power for all drugs. The Medicaid PDL includes many brand and generic medications with robust federal rebates and additional supplemental rebates offered by manufacturers which reduce costs to the Medicaid budget. If numerous physicians prescribe drugs for serious mental illnesses that are not on the PDL, it will result in an increase to drug costs in therapeutic classes for serious mental illness due to a loss of rebate revenues. See Fiscal Comments.

#### 2. Expenditures:

The bill will have an indeterminate, but likely significant negative fiscal impact on expenditures related to the Medicaid program. The bill requirements to pay for drugs currently subject to step therapy requirements means AHCA will pay for more expensive drugs more often, rather than less expensive drugs. See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

Drugs treating serious mental illness accounted for over \$131 million in paid claims in the Medicaid program in 2022.<sup>33</sup> Antidepressants alone were responsible for \$30 million in paid claims, or 23 percent of total paid claims.<sup>34</sup> Antipsychotics are projected to bring \$13 million in rebates in 2023, with a total spend of \$70 million.<sup>35</sup>

AHCA estimated the difference in cost between drugs for serious mental illness on the PDL and nonpreferred drugs for four major categories of medications:

- Tricyclic antidepressants: As of March 2022, 99.9 percent of paid claims in this class were for preferred drugs. Nonpreferred drugs in this therapeutic class can cost 10 times more than the drugs on the PDL.
- Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants: As of June 2022, 99.3 percent of paid claims in this class were for preferred drugs. Nonpreferred drugs in this therapeutic class can cost 22 times more than the drugs on the PDL.
- Other antidepressants: As of June 2022, 99.9 percent of paid claims in this class were for preferred drugs, including oral and injectable medications. The oral nonpreferred antidepressants can be more than 17 times more than drugs on the PDL.
- Antipsychotics: As of September 2022, 98.3 percent of paid claims in this class were for preferred drugs. The step therapy requirement for schizophrenia, schizotypal, and delusional disorder drugs was removed in 2022. After removal, PDL compliance decreased 0.1 percent in this class of drugs. The decrease in compliance resulted in reduced manufacturer rebates, which offset the cost of spending.<sup>36</sup>

AHCA completed an analysis using Florida data modeled to reflect utilization trends in states that are unable to manage the serious mental illness class of drugs. AHCA estimates an increase in drug spend between \$33.7 million and \$53.12 million annually, due to shifts in utilization trends and loss of supplemental rebates.<sup>37</sup>

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to impact county or municipal government.

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<sup>33</sup> Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis – HB 183*, Jan. 5, 2023, pg. 4, (on file with the House Healthcare Regulation Subcommittee).

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

<sup>35</sup> *Id.*, pg. 6.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*, pg. 8.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

Current law provides AHCA sufficient rulemaking authority to implement the provisions of the bill.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES**

On April 3, 2023, the Healthcare Regulation Subcommittee adopted one strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Matched the House bill with the Senate CS bill version.
- Required AHCA to include in the program rates effective October 1, 2023, the rate impact of removing SMI drugs from the step-therapy protocols to Medicaid managed medical assistance and long-term care managed care programs.
- Changed the effective date to October 1, 2023.

The analysis is drafted to the committee substitute as passed by the Healthcare Regulation Subcommittee.