HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: HB 885 Prescription Drugs Used in the Treatment of Schizophrenia for Medicaid Recipients
SPONSOR(S): McFarland and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 534

FINAL HOUSE FLOOR ACTION: 112 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

HB 885 passed the House on March 4, 2022, as SB 534.

The Florida Medicaid program administered by the Agency for Health Care Administration (AHCA) provides prescription drug coverage to approximately 5 million Floridians. Prescription drugs reimbursed in the Medicaid program are subject to federally negotiated manufacturer rebates, and state-negotiated supplemental rebates. The Florida Medicaid Preferred Drug List (PDL), established by AHCA based on recommendations from the Medicaid Pharmacy and Therapeutics Committee, is a list of the most cost-effective drugs in each therapeutic class. The PDL is developed by considering clinical efficacy, safety, and cost.

Under current law, Medicaid requires prior authorization and step therapy for drugs not listed on the PDL. Step therapy requires recipients to first try a PDL-listed drug before obtaining a non-PDL drug, subject to a list of clinical exceptions, which must be documented by the prescriber to obtain prior authorization.

The bill adds additional exceptions to the Medicaid step therapy policy for drugs used to treat schizophrenia, schizotypal or delusional disorders, where:

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

The bill will have an indeterminate but insignificant negative, recurring fiscal impact on AHCA, and no fiscal impact on local government.

The bill was approved by the Governor on April 6, 2022, ch. 2022-27, L.O.F., and will become effective on July 1, 2022.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Florida Medicaid

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.[1] 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.[2] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drug coverage.[3]

The Florida Medicaid program covers approximately 5 million low-income individuals, including approximately 2.5 million, or 58.4%, of the children in Florida.[4] Medicaid is the second largest single program in the state, behind public education, representing approximately one-third of the total Fiscal Year 2021-2022 state budget.[5] Florida's program is the 4th largest in the nation by enrollment and, for FY 2019-2020, the program is the 5th largest in terms of expenditures.[6]

Florida delivers medical assistance to most Medicaid recipients - approximately 78% - using a comprehensive managed care model.[7] While current law requires provision of all Medicaid covered services for these recipients through this managed care model,[8] 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.[9] 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.[10] AHCA contracts with a pharmacy benefit manager to negotiate those rebates. Total federal and state rebate revenue for Fiscal Year 2021-2022 is projected to be $2.15 billion, which is 58 percent of the total Medicaid prescription drug spend of $3.7 billion this year. These revenues are reinvested in the Medicaid program.

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[1] Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725).
[2] S. 409.905, F.S.
[3] S. 409.906, F.S.
[4] Agency for Health Care Administration, *Florida Statewide Medicaid Monthly Enrollment Report*, Dec. 2021, available at https://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Jan. 18, 2022). United States Census Bureau, *QuickFacts, Florida*, https://www.census.gov/quickfacts/fact/table/FL/PST045221 (last visited Jan. 18, 2022).
[5] Ch. 2020-111, L.O.F. See also *Fiscal Analysis in Brief: 2021 Legislative Session*, available at http://edr.state.fl.us/content/revenues/reports/fiscal-analysis-in-brief/FiscalAnalysisinBrief2021.pdf (last visited Jan. 6, 2022).
[6] The Henry J. Kaiser Family Foundation, *State Health Facts, Total Medicaid Spending FY 2020 and Total Monthly Medicaid and CHIP Enrollment Jun. 2021*, available at http://kff.org/statedata/ (last visited Jan. 18, 2022).
[7] S. 409.964, F.S.
[8] S. 409.964, F.S.
[9] Title 42 U.S.C. § 1396r-8. State Medicaid programs are authorized to cover non-rebated drugs with HHS approval, under certain circumstances.
[10] S. 409.912(5)(a), F.S.

Also 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.[11] 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.[12] 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.[13]

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 (or managed care plan) approval prior to dispensing, or Medicaid will not pay for the drug.[14] AHCA may require prior authorization:[15]

- 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.[16] 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.[17]

Coverage of Prescription Drugs for Schizophrenia, Schizotypal and Delusional Disorders

The Medicaid PDL includes numerous generic and brand name drugs for the treatment of 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[18], and includes those guidelines with the prior authorization criteria it publishes online for prescribers.[19]

In 2018-2020, 108,670 Medicaid recipients had diagnosed schizophrenia, schizotypal or delusional disorders. For that period, 6,313 requests for prior authorization were made for medications to treat those conditions. Of those, 74 were denied, and 457 resulted in a change in therapy. In that time, Medicaid spent $497,270,227 on medications to treat schizophrenia, schizotypal or delusional disorders, for 2.37 million claims, including 2.3 million PDL drug claims and 50,836 non-PDL drug claims.[20]

Prescribed Drug Step Therapy

[11] S. 409.912(5)(a), F.S. *See*, Florida Medicaid Preferred Drug List, Agency for Health Care Administration, Jan. 14, 2022, available at https://ahca.myflorida.com/medicaid/prescribed_drug/pharm_thera/fmpdl.shtml (last visited Feb. 6, 2022).
[12] SS. 409.912(5)(a)7., 409.91195(7), F.S.
[13] 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).
[14] S. 409.91195(5), F.S.
[15] S. 409.912(5)(a)12., F.S.
[16] *Id.*
[17] S. 409.912(5)(a), F.S.
[18] 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) (last visited Feb. 6, 2022).
[19] Agency for Health Care Administration, Drug Criteria, available at Drug Criteria (myflorida.com) (last visited Feb. 6, 2022); Agency for Health Care Administration, Agency Legislative Bill Analysis for SB 534, Nov. 22, 2021.
[20] Email correspondence, Agency for Health Care Administration, Feb. 2, 2022 (on file with the Finance and Facilities Subcommittee) Total spend include both fee-for-service and managed care expenditures.

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.[21] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[22] Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[23] while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[24]

Commercial Insurance Step Therapy Regulation

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.[25]

Medicaid Step Therapy Requirements

[21] 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 visited Nov. 28, 2021).
[22] 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 visited Nov. 23, 2021).
[23] *Supra* note 21 at pg. 1780.
[24] Id.
[25] Ss. 627.42393, 641.31(46), F.S.

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.[26] The step-therapy policy does not apply if the prescriber provides medical or clinical documentation showing:[27]

- 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.

Effect of Proposed Changes

The bill amends current Medicaid law related to the use of step therapy for prescription drug benefits. Specifically, it creates an additional 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.

A significant reduction in the use of PDL drugs will result in lower manufacturer rebate revenue to AHCA. It is currently unknown how many Medicaid recipients were subject to step therapy for prescription drugs to treat these conditions. However, the vast majority of prior authorization requests for non-PDL drugs are approved, which indicates the number may be insignificant. Similarly, while 457 prior authorization requests resulted in a change in therapy (over a three-year period), it is unknown how many were for drugs to treat these conditions or how many were due to the step therapy policy.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Limitations on the use of step therapy may result in lower drug manufacturer rebates rendered to AHCA, in an indeterminate amount.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[26] S. 409.912(5)(a)14., F.S.
[27] *Id.*

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.