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 Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 1292
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Medicaid
DATE:	April 7, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Fav/CS**
2.	McKnight	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1292 updates or repeals outdated or obsolete language relating to:

- Reimbursement of prescribed drugs based on average wholesale price;
- Implementation of, including increases and decreases to, a variable pharmacy dispensing fee;
- Review of certain drugs by the Medicaid Pharmaceutical and Therapeutics Committee;
- Duties of the Department of Children and Families regarding Medicaid Fair Hearings;
- Providing prior "authorizations" rather than "consultations" for pharmacy services;
- Expansion of mail order delivery of pharmacy products;
- Medicaid reimbursement of drugs prescribed to treat erectile dysfunction;
- The definition of "medical necessity;" and
- The Organ Transplant Advisory Council.

The bill also eliminates requirements that the Agency for Health Care Administration (AHCA) submit reports to the Legislature that are obsolete or outdated related to the Pharmaceutical Expense Assistance Program, the Medicaid Reform 1115 Waiver, and Fee-for-Service Pharmaceutical spending.

The bill does not have a fiscal impact on the Florida Medicaid program. *See* Section V of this analysis.

The bill takes effect on July 1, 2021.

II. Present Situation:

Due to the diverse range of issues within the bill, additional background information is provided within the effect of proposed changes section of this analysis for the reader's convenience.

The Agency for Health Care Administration

The Agency for Health Care Administration (AHCA) is the chief health policy and planning entity for the state and is responsible for, among other things, the administration of the Florida Medicaid program, and health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies, and licenses, certifies, regulates or provides exemptions for more than 48,000 providers.[1]

Florida Medicaid Program

The Medicaid program is a partnership between the federal and state governments that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities.[2] The federal Centers for Medicare and Medicaid Services (CMS) within the United States Department of Health and Human Services is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians and is administered by the AHCA, and financed through state and federal funds.[3]

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. States send state plan amendments to the federal CMS for review and approval.[4]

Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service (FFS) or managed care. Under FFS, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. Under managed care, the AHCA contracts with private managed care plans for the coordination and payment of services

[1] *See* Agency for Health Care Administration (AHCA), Division of Health Quality Assurance *available at* http://ahca.myflorida.com/MCHQ/index.shtml (last visited Mar. 31, 2021).
[2] Medicaid.gov, *Medicaid*, *available at* https://www.medicaid.gov/medicaid/index.html (last visited Mar. 3, 2021).
[3] Section 20.42, F.S.
[4] Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Mar. 3, 2021).

for Medicaid enrollees. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan.

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.[5] The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care program. Florida's SMMC offers a health care package covering both acute and long-term care.[6] 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 August 2014, and the current contracts expire in 2024.[7]

III. Effect of Proposed Changes:

Pharmaceutical Expense Assistance Program Report

The Pharmaceutical Expense Assistance Program was established within the AHCA in 2006 to provide pharmaceutical expense assistance to individuals diagnosed with cancer or individuals who have received organ transplants who were medically needy recipients prior to January 1, 2006, and who are eligible for Medicare.[8] Using Medicaid payment policies, the AHCA pays Medicare Part B prescription drug coinsurance and deductibles for Medicare Part B medications that treat eligible cancer and organ transplant patients.[9]

The initial program was funded with $3.7 million and approximately 650 people were identified as potentially eligible for the program. Only those unique individuals identified as eligible at the time of the program's passage are eligible and, as a result, program size and expenditures have reduced significantly. The program currently pays pharmacy expenses for approximately 20 individuals who meet that criteria, requiring a total expenditure of $4,457 during Fiscal Year 2019-2020.[10]

The AHCA is currently required to submit an annual report to the Legislature on the operation of the program. The annual report must include information on the number of individuals served, use rates, and expenditures under the program.

Section 1 of the bill amends s. 402.81, F.S., to eliminate the requirement that the AHCA submit a report to the Legislature by January 1 of each year on the operation of the Pharmaceutical Expense Assistance Program.

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[5] Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Mar. 3, 2021).
[6] *Id.*
[7] Chapter 2020-156, s. 44, Laws of Fla.
[8] Chapter 2006-28, s. 20, Laws of Fla.; Section 402.81(1) and (2), F.S.
[9] Section 402.81(3), F.S.
[10] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

Drug Pricing Formula

The AHCA is required to reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in agency rule.[11] Florida law specifies that a provider of prescribed drugs must be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the AHCA, plus a dispensing fee.[12]

On February 1, 2016, the federal CMS published a final rule, effective April 1, 2017, that requires states to update reimbursement methodologies for covered outpatient drugs in the Medicaid program.[13] The requirements of this rule include a revised federal regulation requiring states to reimburse at an aggregate upper limit based on actual acquisition cost plus a professional dispensing fee established by the state Medicaid agency.[14]

While states retained the flexibility to establish reimbursement methodologies consistent with the requirements of this final rule, Florida's statutory reimbursement methodology does not align with the new federal requirements. In response, the AHCA amended its reimbursement methodology for covered outpatient drugs.[15] Changes in the bill would update the statutory reimbursement methodologies so they are in line with the federal rules and with the AHCA's current practice.[16]

Section 3 of the bill amends s. 409.908(14), F.S., and **Section 5** of the bill amends s. 409.912(5)(a), F.S., to make changes to provisions setting reimbursement rates for providers of prescribed drugs. Currently, a provider of prescribed drugs must be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost must be based on the lowest of: the average wholesale price minus 16.4 percent, the wholesaler acquisition cost plus 1.5 percent, the federal upper limit, the state maximum allowable cost, or the usual and customary charge billed by the provider. Under the bill, a provider of prescribed drugs will be reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the federal CMS National Average Drug Acquisition Cost pricing files plus a professional dispensing fee, the wholesale acquisition cost plus a professional dispensing fee, the state maximum allowable cost plus a professional dispensing fee, or the usual and customary charge billed by the provider.

Section 4 of the bill reenacts s. 409.91195(4), F.S., to incorporate the changes made to s. 409.912(5)(a), F.S.

[11] Section 409.908, F.S.
[12] Sections 409.908(14) and 409.912(5)(a), F.S.
[13] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).
[14] 42 CFR s. 447.512(b)
[15] Fla. Admin. Code R. 59G-4.251 (2020).
[16] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

Variable Dispensing Fee

In addition to reimbursement for a prescription drug's cost, Medicaid pays pharmacies a professional dispensing fee for filling the prescription.

The AHCA is currently required to implement a variable dispensing fee for prescribed drugs. The AHCA is authorized to increase the dispensing fee by $0.50 for the dispensing of a drug on the Medicaid preferred drug list and to reduce the dispensing fee by $0.50 for drugs not on the preferred drug list.[17]

Effective April 1, 2017, federal CMS implemented the use of the term "professional dispensing fee" and mandated that certain criteria be met in setting the dispensing fee.[18] In response, the AHCA updated the Medicaid state plan with a new professional dispensing fee that does not conform to s. 409.908(14)(b) and (c), F.S. **Section 3** of the bill deletes these obsolete paragraphs.

Medicaid Preferred Drug List and Patient Safety

Established in 2000, the Medicaid Pharmaceutical and Therapeutics Committee (Committee) is composed of four allopathic physicians, one osteopathic physician, five pharmacists, and a consumer representative, each appointed by the Governor.[19] The Committee must meet at least quarterly and is responsible for developing, implementing, updating, and providing the AHCA with the Medicaid Preferred Drug List.[20]

Section 4 of the bill amends s. 409.91195(9), F.S., to remove language requiring the AHCA to ensure that any therapeutic class of drugs, including drugs that have been removed from distribution to the public by their manufacturer or the federal Food and Drug Administration (FDA) or have been required to carry a black box warning label by the federal FDA because of safety concerns, is reviewed by the Committee at the "next regularly scheduled meeting." Under current law, after such review, the Committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the Medicaid preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.

If drugs covered by Florida Medicaid are removed from distribution for safety reasons or because of an FDA-mandated black box warning, the AHCA does not wait for the quarterly committee meetings or for its recommendations because the safety of enrollees could be at stake.[21]

Medicaid Fair Hearings

Individuals who have been turned down for a Medicaid service, or who were receiving a Medicaid service that has been was reduced or stopped, should receive a letter explaining why

[17] Section 409.908(14), F.S.
[18] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).
[19] AHCA, *Medicaid Pharmaceutical & Therapeutics Committee*, *available at* https://ahca.myflorida.com/medicaid/prescribed_drug/pharm_thera/ (last visited Mar. 22, 2021). *See* s. 409.91195, F.S.
[20] *Id.*
[21] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

Medicaid will not pay for or cover the service.[22] In these cases, the individual has the right to challenge that determination in a Medicaid fair hearing.[23] Medicaid fair hearing responsibilities were moved from the Department of Children and Families (DCF) to the AHCA in 2016.[24]

Section 4 of the bill amends s. 409.91195(10), F.S., to reflect that the AHCA is responsible for Medicaid fair hearings in which preferred drug formulary decisions are appealed, rather than the DCF.

Prior Consultation and Prior Authorization

The AHCA is required to establish procedures ensuring that there is a response to a request for prior consultation by telephone or other communication device within 24 hours after receipt of a request for prior consultation.[25] Prior authorization means a process by which a health care provider must qualify for payment coverage by obtaining advance approval from a health plan before a specific service is delivered to the patient.[26]

Section 5 of the bill amends that provision to change prior "consultation" to prior "authorization." The AHCA does not provide pharmacy consultations, as that responsibility lies with the pharmacist.[27]

Home Delivery of Pharmacy Products

Since 2011, the AHCA has been required to "expand" home delivery of pharmaceuticals.[28] This provision predates the implementation of the SMMC program and the current Medicaid Pharmacy services rule.[29] The AHCA reports that this language is no longer needed because Medicaid FFS and managed care plans already provide for mail order delivery of drugs.

Section 5 deletes the outdated provisions requiring the AHCA to expand home delivery of pharmacy products.

Erectile Dysfunction Drugs

In 2005, federal law was amended to prohibit Medicaid federal financial participation for drugs used for the treatment of sexual or erectile dysfunction, unless such drugs were approved by the federal Food and Drug Administration to treat a different condition.[30] The Florida Medicaid

[22] AHCA, *Medicaid Fair Hearings, available at* https://ahca.myflorida.com/medicaid/complaints/fair_hrng.shtml (last visited Mar. 22, 2021).
[23] *Id.*
[24] Chapter 2016-65, Laws of Fla.
[25] Section 409.912(5)(a), F.S
[26] 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 Mar. 22, 2021).
[27] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy)..
[28] Section 409.912(5)(a), F.S.
[29] *Id.*
[30] *Id.*

program is currently authorized to reimburse any drug prescribed to treat erectile dysfunction, limited to one dose per month.[31] This authorization predates the federal prohibition.

Section 5 deletes the provision limiting the doses of sexual or erectile dysfunction drugs, as Florida Medicaid does not cover such drugs based on the 2005 prohibition.

Medicaid Fee-for-Service Pharmaceutical Quarterly Report

The AHCA is currently required to submit quarterly reports to the Legislature on the implementation of a Medicaid prescribed-drug spending-control program for the FFS delivery system.[32] The reporting requirement has been in place since 2010 and pre-dates the implementation of the SMMC program and therefore, the cost controls described are no longer applicable to most Medicaid recipients in Florida. Fee-for-service Medicaid recipients are typically not enrolled in managed care due to specific health needs, the presence of other insurance, or because they are living in a facility that provides their prescription drugs. The results of the report do not generally reflect the Medicaid population.

Section 5 eliminates the requirement that the AHCA report quarterly to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the progress made on implementing s. 409.912(5), F.S., relating to Medicaid prescribed drug spending and its effect on expenditures.

Medicaid Reform 1115 Waiver Report

The AHCA is required to submit to the Legislature quarterly progress reports and annual reports that are submitted to the federal CMS for the 1115 Managed Medical Assistance waiver which is tied to the original 2006 Medicaid Reform waiver authority. The Medicaid Reform pilot program ended in 2014 with the full implementation of the SMMC program. These reports are now obsolete. All federal CMS-mandated reports regarding the SMMC waiver are posted on the AHCA's website to ensure transparency about the waiver.[33]

Section 6 of the bill repeals s. 409.91213, F.S., to eliminate the requirement that the AHCA submit a quarterly progress report and an annual report relating to the 1115 Managed Medical Assistance waiver to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Minority Leader of the Senate, the Minority Leader of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability.

[31] Section 409.912(5)(a), F.S.
[32] Section 409.912 (5)(c), F.S.
[33] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

Medical Necessity

Federal law specifies that state Medicaid programs do not have to cover services that are not medically necessary.[34] Each state has adopted its own definition of "medical necessity."[35] 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, based upon information available *at the time the goods or services are provided*.

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.

Section 7 of the bill amends s. 409.913, F.S., to create an exception to the requirement that determinations of medical necessity must be made by a licensed physician employed by or under contract with the AHCA. The exception enables doctoral-level, board-certified behavior analysts to make determinations of medical necessity for behavior analysis services in addition to licensed physicians. The bill also requires a determination of medical necessity to be based on information available at the time the goods or services are requested, rather than when they are provided. This change will bring Florida law into line with federal regulations.[36]

Organ Transplant Advisory Council

Section 765.53, F.S., establishes the Organ Transplant Advisory Council (OTAC) to consist of 12 physician members who are appointed to represent the interests of the public and the clients of the Department of Health or the AHCA. All members are appointed by the Secretary of Health Care Administration for two-year terms. The OTAC is responsible for recommending indications for adult and pediatric organ transplants to the AHCA and formulating guidelines and standards for organ transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The OTAC's recommendations, guidelines, and standards are limited in applicability to only those health programs funded through the AHCA.

[34] 42 U.S.C. s. 1395y.
[35] 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 viewed Mar. 22, 2021).
[36] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

The OTAC met 22 times with its first meeting held on August 27, 2007, and its last meeting held on April 14, 2015.[37]

Most actions of the OTAC revolved around approving guidelines for organ transplantations and reviewing and approving hospital transplant program applications for recommendation to the AHCA, which have been adopted into rule and into the Medicaid State Plan.[38] The AHCA indicates that the duties and responsibilities of the OTAC have become redundant because of federal CMS oversight, the Organ Procurement and Transplantation Network, the federal Health Resources and Services Administration, the United Network for Organ Sharing, Organ Procurement Organizations, the Foundation for the Accreditation of Cellular Therapy, and the Joint Commission.[39] The non-statutory function of the OTAC (recommending approval of transplant programs to the Secretary of Health Care Administration for Medicaid-designation) could be undertaken by staff of the AHCA.[40]

Section 8 of the bill repeals s. 765.53, F.S., to dissolve the OTAC by eliminating its statutory authority. **Section 2** of the bill amends s. 409.815, F.S., to delete a reference to the OTAC which would be dissolved under such repeal.

Section 9 of the bill provides an effective date of July 1, 2021.

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.

[37] AHCA, *Organ Transplant Advisory Council Meeting Information*, *available at* https://ahca.myflorida.com/medicaid/organ_transplant/meetings.shtml (last viewed Mar. 19, 2021).
[38] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).
[39] *Id.*
[40] *Id.*

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The AHCA reports that the bill will not have a fiscal impact on the Medicaid program, nor have any impact on recipients or providers.[41]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 402.81, 409.815, 409.908, 409.91195, 409.912, and 409.913.

This bill repeals the following sections of the Florida Statutes: 409.91213 and 765.53.

IX. Additional Information:

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

CS by Health Policy on March 24, 2021:
The CS reinstates the current requirement in s. 409.908(2)(b), F.S., for the AHCA to submit an annual report related to nursing home direct and indirect care costs to the Legislature.

The CS also reinstates the current requirement in s. 409.913(d), F.S., that a determination of medical necessity must be made by a licensed physician, but also creates an exception for behavior analysis services by authorizing a doctoral-level, board-certified behavior analyst to make a determination of medical necessity, in addition to a licensed physician. The CS also reinstates and revises the current requirement for a determination of medical necessity to be based upon information available at the time the goods and services are "requested," rather than when they are "provided."

[41] AHCA, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.

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