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 1292
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Medicaid
DATE:	March 24, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Fav/CS**
2.			AHS	
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CS/SB 1292 updates or repeals outdated or obsolete language relating to the:

- Expansion of the mail order delivery of pharmacy products;
- 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;
- Definition of "medical necessity;"
- Medicaid reimbursement of drugs prescribed to treat erectile dysfunction;
- Duties of the Department of Children and Families regarding Medicaid Fair Hearings; and
- The Organ Transplant Advisory Council (OTAC).

The bill also eliminates requirements that the Agency for Health Care Administration (AHCA) submit the following to the Legislature:

- Annual report related to the Pharmaceutical Expense Assistance Program;
- Quarterly reports related to the Medicaid Reform 1115 Waiver; and
- Quarterly reports related to fee-for-service pharmaceutical spending.

The AHCA reports that the bill will not have a fiscal impact on the Medicaid program, nor have any impact on recipients or providers.[1]

[1] Agency for Health Care Administration, *Senate Bill 1292 Fiscal Analysis* (Feb. 19, 2021) (on file with the Senate Committee on Health Policy).

The bill provides an effective date of July 1, 2021.

II. Present Situation:

Due to the diverse 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 AHCA is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, 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. In total, the AHCA licenses, certifies, regulates or provides exemptions for more than 48,000 providers.[2]

Florida Medicaid Program

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities.[3] The Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians. Florida's program is administered by the AHCA and financed through state and federal funds.[4]

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.[5]

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

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[2] *See* Agency for Health Care Administration, Division of Health Quality Assurance *available at* http://ahca.myflorida.com/MCHQ/index.shtml (last visited Jan. 23, 2020).
[3] Medicaid.gov, *Medicaid*, *available at* https://www.medicaid.gov/medicaid/index.html (last visited Mar. 3, 2021).
[4] Section 20.42, F.S.
[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).

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.[6] 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.[7] 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 was re-procured for a period beginning December 2018 and ending in 2023.[8]

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.[9] 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.[10]

Section 1 of the bill amends s. 402.81, F.S., to eliminate the requirement that the AHCA report to the Legislature by January 1 of each year on the operation of Pharmaceutical Expense Assistance Program. Currently, the annual report must include information on the number of individuals served, use rates, and expenditures under the program.

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.[11]

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.[12] Currently, ss. 409.908(14) and 409.912(5)(a), F.S., specify that a provider of prescribed drugs must be reimbursed the least of

[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Chapter 2006-28, s. 20, Laws of Fla., Section 402.81(1) and (2), F.S.
[10] Section 402.81(3), F.S.
[11] *Supra* note 1.
[12] Section 409.908, F.S.

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.

On February 1, 2016, the federal Centers for Medicare & Medicaid Services (CMS) published the Covered Outpatient Drug final rule, CMS-2345-FC, effective April 1, 2017. This rule required states to submit a State Plan Amendment by June 30, 2017, to update reimbursement methodologies for covered outpatient drugs in the Medicaid program.[13] The requirements of this rule included a revised requirement from 42 CFR s. 447.512(b) for states to reimburse at an aggregate upper limit based on actual acquisition cost plus a professional dispensing fee established by the state Medicaid agency.

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.[14] 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.[15]

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 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.

Variable Dispensing Fee

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

Currently, paragraph (b) of s. 409.908(14), F.S., requires the AHCA to implement a variable dispensing fee for prescribed drugs. Paragraph (c) of that subsection authorizes the AHCA 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.

[13] *Supra* note 1.
[14] Fla. Admin. Code R. 59G-4.251 (2020).
[15] *Supra* note 1.

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.[16] 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.

Prior Consultation and Prior Authorization

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.[17]

Currently, s. 409.912(5)(a), F.S., requires the AHCA 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. **Section 5** of the bill amends that provision to change prior "consultation" to prior "authorization." The AHCA does not provide pharmacy consultations (that is the role of the pharmacist), and legal counsel for the agency has recommended that this be interpreted to mean prior authorization and not prior consultation.[18]

Home Delivery of Pharmacy Products

Section 5 of the bill deletes outdated provisions requiring the AHCA to expand home delivery of pharmacy products. These provisions have been in place since 2011, predating the implementation of the SMMC program and the current Medicaid Pharmacy services rule.[19] 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.

Erectile Dysfunction Drugs

In 2005, Section 1903(i) of the Social Security Act 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 FDA to treat a different condition.[20] Subparagraph 9. of s. 409.912(5)(a), F.S., authorizes Medicaid to reimburse any drug prescribed to treat erectile dysfunction, limited to one dose per month. This subparagraph predates the federal prohibition.

Medicaid FFS Pharmaceutical Quarterly Report

Section 5 of the bill amends s. 409.912(5)(c), F.S., to eliminate 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. The quarterly report applies only to the FFS delivery system, which excludes the majority of Medicaid recipients in managed care. FFS

[16] *Supra* note 1.
[17] 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).
[18] *Supra* note 1.
[19] *Id.*
[20] *Id.*

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. Because of this, the AHCA reports that the results of the report are not generally reflective of the Medicaid population.

Medicaid Preferred Drug List and Patient Safety

Established in 2000, the Medicaid Pharmaceutical and Therapeutics Committee (Committee) as authorized in s. 409.91195, F.S., is composed of four allopathic physicians, one osteopathic physician, five pharmacists, and a consumer representative, each appointed by the Governor.[21] The Committee must meet at least quarterly and is responsible for developing, implementing, updating, and providing the AHCA with the Medicaid Preferred Drug List.[22]

Section 4 of the bill also 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.[23]

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 Medicaid will not pay for or cover the service.[24] In these cases, the individual has the right to challenge that determination in a Medicaid fair hearing.[25] Medicaid fair hearing responsibilities were moved from the Department of Children and Families (DCF) to the AHCA in the 2016 Legislative session.[26] **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.

[21] Agency for Health Care Administration, 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.
[22] *Id.*
[23] *Supra* note 1.
[24] Agency for Health Care Administration, Medicaid Fair Hearings *available at* https://ahca.myflorida.com/medicaid/complaints/fair_hrng.shtml (last visited Mar. 22, 2021).
[25] *Id.*
[26] Ch. 2016-65, Laws of Fla.

Medicaid Reform 1115 Waiver Report

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. The Medicaid Reform 1115 waiver is tied to the original 2006 Medicaid Reform waiver authority. The Medicaid Reform pilot program ended in 2014 with the full implementation of the Statewide Medicaid Managed Care Program. Because of this, the AHCA considers this report to be obsolete.[27] The AHCA notes that all CMS-mandated reports regarding the SMMC waiver are posted on its website.[28]

Medical Necessity

Federal law specifies that state Medicaid programs do not have to cover services that are not medically necessary.[29] Each state has adopted its own definition of "medical necessity."[30] 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

[27] *Supra* note 1.
[28] *Id.*
[29] 42 U.S.C. s. 1395y.
[30] 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).

information available at the time the goods or services are requested, rather than when they are provided.

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 (DOH) 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.
The OTAC met 22 times with its first meeting held on August 27, 2007, and its last meeting held on April 14, 2015.[31]

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.[32] The AHCA indicates that the duties and responsibilities of the OTAC have become redundant because of the oversight of the federal CMS, 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.[33] 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.[34]

Section 8 of the bill repeals s. 765.53, F.S., to dissolve the Organ Transplant Advisory Council by eliminating its statutory authority. **Section 2** of the bill amends s. 409.815, F.S., to delete a reference to the Organ Transplant Advisory Council 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.

[31] Agency for Health Care Administration, Organ Transplant Advisory Council Meeting Information, *available at* https://ahca.myflorida.com/medicaid/organ_transplant/meetings.shtml (last viewed Mar. 19, 2021).
[32] *Supra* note 1.
[33] *Id.*
[34] *Id.*

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.

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.[35]

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, and 409.913.

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

This bill reenacts section 409.912 of the Florida Statutes.

[35] *Id.*

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."

B. Amendments:

None.