HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 1057 Agency for Health Care Administration
SPONSOR(S): Finance & Facilities Subcommittee, Garrison
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1292

FINAL HOUSE FLOOR ACTION: 118 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 1057 passed the House on April 15, 2021, and subsequently passed the Senate on April 26, 2021.

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. AHCA delegates certain functions to other state agencies, including the Department of Children and Families, which makes eligibility determinations. Florida uses a comprehensive managed care delivery model for primary and acute care services to serve the bulk of its Medicaid population, known as the Statewide Medicaid Managed Care (SMMC) Managed Medical Assistance (MMA) program. A minority of Medicaid recipients continue to receive services under a fee-for-service (FFS) model of care.

The bill modifies AHCA duties under the Medicaid program by eliminating legislative reporting requirements. In particular, the bill eliminates the following reports without changing the relevant program responsibilities:

- A quarterly progress report detailing activities involved with the transition from traditional Medicaid programming to Medicaid managed care;
- An annual report to the Legislature on the operation of the pharmaceutical expense assistance program for individuals dually-eligible for Medicaid and Medicare; and,
- A quarterly report to the Legislature on the progress of the drug spending control program for FFS Medicaid recipients.

The bill also makes changes to reflect federal Medicaid requirements and AHCA practices. Specifically, the bill:

- Revises FFS drug reimbursement benchmarks in compliance with revised federal Medicaid regulations;
- Modifies the duties of the Pharmacy & Therapeutics Committee regarding drug safety bulletins issued by the federal Food & Drug Administration and drug manufacturers;
- Clarifies that AHCA must timely respond to requests for "authorizations" associated with prescribed drugs under the FFS program, rather than responding to requests for "consultations";
- Deletes obsolete language directing AHCA to expand home delivery of pharmacy products;
- Removes language limiting coverage of drugs prescribed for a specified condition, consistent with federal Medicaid policy;
- Corrects an inaccurate reference to the Medicaid fair hearing process administered by AHCA;
- Expands the range of practitioners that may make medical necessity determinations; and,
- Eliminates the Organ Transplant Advisory Council.

The bill has no fiscal impact on state or local government.

The bill was approved by the Governor on June 21, 2021, ch. 2021-151, L.O.F., the bill takes effect on July 1, 2021.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Florida Medicaid Program

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. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), which makes eligibility determinations.

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] Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states. The federal government sets the minimum mandatory populations to be included in every state Medicaid program. The federal government also sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[2] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, ambulatory surgical center services, and dialysis.[3]

Florida Medicaid does not cover all low-income Floridians. Eligibility is determined by household income and by certain categorical eligibility standards, like disability.

The Florida Medicaid program covers approximately 4.5 million low-income individuals.[4] Medicaid is the second largest single program in the state, behind public education, representing approximately one-third of the total FY 2020-2021 state budget.[5]

Medicaid Managed Care

States have some flexibility in the provision of Medicaid services. Section 1915(b) of the Social Security Act provides authority for the Secretary of the U.S. Department of Health and Human Services to waive requirements to the extent that he or she "finds it to be cost-effective and efficient and not inconsistent with the purposes of this title." Also, Section 1115 of the Social Security Act allows states to use innovative service delivery systems that improve care, increase efficiency, and reduce costs.

States may also ask the federal government to waive federal requirements to expand populations or services, or to try new ways of service delivery. Many states have elected to provide Medicaid benefits through a managed care model. Traditionally, Medicaid services are paid for under a fee-for-service (FFS) reimbursement model. Under the FFS model, the state pays providers directly for each covered service received by a Medicaid beneficiary. Under managed care, the state pays a fee to a managed care plan for each person enrolled in the plan. In turn, the plan pays providers for all of the Medicaid services a beneficiary may require that are included in the plan's contract with the state.[6]

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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) (2016).
[2] S. 409.905, F.S.
[3] S. 409.906, F.S.
[4] Agency for Health Care Administration, *Florida Statewide Medicaid Monthly Enrollment Report*, December 2020, available at https://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last accessed May 3, 2021).
[5] Ch. 2020-111, L.O.F. See also *Fiscal Analysis in Brief: 2020 Legislative Session*, available at https://flsenate.gov/UserContent/Committees/Publications/FiscalAnalysisInBrief/2020_Fiscal_Analysis_In_Brief.pdf (last accessed May 3, 2021).
[6] Medicaid and CHIP Payment and Access Commission (MACPAC), *Provider payment and delivery systems*, https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/ (last accessed May 3, 2021).

For example, Florida has a Section 1115 waiver to use a comprehensive managed care delivery model for primary and acute care services, the Statewide Medicaid Managed Care (SMMC) Managed Medical Assistance (MMA) program.[7] The MMA program was enacted in 2011 and fully implemented in 2014.

MMA Program

The MMA program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state.[8] Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans. Roughly 80% of Florida's Medicaid population is served through the MMA program, while the remainder of participants are served by traditional FFS Medicaid.[9]

Most Medicaid recipients must be enrolled in the MMA program. Those individuals who are not required to enroll, but may choose to do so, are:

- Recipients who have other creditable coverage, excluding Medicare;
- Recipients who reside in residential commitment facilities through the Department of Juvenile Justice or mental health treatment facilities;
- Persons eligible for refugee assistance;
- Residents of a developmental disability center;
- Enrollees in the developmental disabilities home- and community-based waiver or those waiting for waiver services; and
- Children in a prescribed pediatric extended care center.[10]

Other Medicaid enrollees are exempt from the MMA program and receive Medicaid services on a fee-for-service basis. Exempt enrollees are:

- Women who are eligible for family planning services only;
- Women who are eligible only for breast and cervical cancer services; and
- Persons eligible for emergency Medicaid for aliens.

Medicaid Reporting Requirements

Current law requires AHCA to publish numerous reports on health care data under the Medicaid program. Some of the reports no longer provide significant data, and others are no longer necessary because data is available online or in other forms.

Medicaid Managed Care Transition Report

Current Situation

[7] S. 409.964, F.S.
[8] Agency for Health Care Administration, *SMMC Region Map*, https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/SMMC_Region_map.pdf (last accessed May 3, 2021).
[9] Agency for Health Care Administration, presentation by Beth Kidder, Deputy Secretary for Medicaid, to the House Health and Human Services Committee, February 17, 2021, https://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=3085&Session=2021&DocumentType=Meeting%20Packets&FileName=hhs%202-17-21.pdf (last accessed May 3, 2021).
[10] S. 409.972, F.S.

Current law requires AHCA to submit to the Legislature a quarterly progress report detailing activities involved with the transition from traditional Medicaid programming to Medicaid managed care.[11] This report is also submitted to the federal Centers for Medicare and Medicaid Services (CMS) to demonstrate the program's progress in meeting the requirements of the Section 1115 waiver authorizing the MMA program.

Effect of the Bill – Medicaid Managed Care Transition Report

The bill deletes this reporting requirement, as the transition to Medicaid managed care was completed in 2014. Moreover, the content and frequency of reporting on the MMA waiver are dictated by CMS and have changed periodically, making them out of synch with statutory requirements. All reports related to the waiver are posted on the Agency's web page.[12]

Pharmaceutical Expense Assistance Program Report

Current Situation

Current law requires AHCA to provide pharmaceutical expense assistance to certain individuals diagnosed with cancer or individuals who have received organ transplants. In order to be eligible for this financial assistance, an individual must have been eligible for the Medically Needy component of Medicaid prior to January 1, 2006.[13] The Medically Needy program provides assistance to individuals who would otherwise be eligible for Medicaid except that their family income or assets exceeds the traditional program thresholds.[14] In addition, an individual must also be eligible for Medicare in order to participate in the pharmaceutical expense assistance program.[15] AHCA must provide an annual report to the Legislature on the operation of the program. The report includes information on the number of individuals served, use rates, and expenditures under the program.[16]

The pharmaceutical expense program was created to assist eligible individuals with cancer or having had organ transplants pay for drugs covered under Part B of the Medicare program. But because program recipients must have been Medicaid-eligible prior to 2006, the size of the program has declined dramatically over the years. AHCA reports that approximately 650 individuals were eligible for the program upon its establishment in 2006. By 2020, only 14 individuals were still eligible to receive assistance under the program.[17]

Effect of the Bill – Pharmaceutical Expense Assistance Program Report

The bill eliminates the reporting requirement under s. 402.81(4), F.S. The pharmaceutical expense assistance program will continue to serve eligible individuals, but the agency will not be required to provide an annual report to the Legislature.

Medicaid Drug Spending Control Program Report

Current Situation

[11] S. 409.91213, F.S.
[12] Agency for Health Care Administration, *Agency Analysis of HB 1057*, March 3, 2021. *See also* Agency for Health Care Administration, "Managed Medical Assistance," https://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/mma_fed_auth.shtml (last accessed May 3, 2021).
[13] S. 402.81, F.S.
[14] S. 409.904(2), F.S.
[15] *Supra* note 12.
[16] S. 402.81(4), F.S.
[17] *Supra* note 12.

Current law requires AHCA to implement a prescribed drug spending control program for the Medicaid population. The program requires AHCA to develop and maintain a preferred drug list, establish a network of pharmacies in the Medicaid program, and use techniques to actively manage the drug utilization of Medicaid recipients.[18] AHCA must submit quarterly reports to the Legislature on the progress of the drug spending control program and its effects on Medicaid drug spending.[19] The program was in place before the development of the MMA program, and now applies only to the FFS population.

Roughly 20% of the Medicaid population is served by the FFS delivery model. This population is primarily made up of individuals who are eligible for both Medicaid and Medicare; that is, over 65 or eligible for Medicare by virtue of a disability and receive only a limited benefit under Medicaid. FFS Medicaid also includes other individuals who receive limited benefits under Medicaid.[20] These populations are not enrolled in health plans because of very specific health needs, the presence of other insurance, or by virtue of living in a facility that provides their prescription drugs, such as a nursing home or intermediate care facility for individuals with developmental disabilities. In other words, this population is very different from the larger MMA population and has very different drug utilization patterns.[21] Thus, it is unclear if drug spending data for the FFS population are reflective of spending trends for the broader Medicaid population.

Effect of the Bill – Medicaid Drug Spending Control Program Report

The bill eliminates the requirement for AHCA to submit quarterly reports to the Legislature on the FFS Medicaid drug spending control program. Since the cost controls required under the program are no longer applicable to most Medicaid recipients, the report provides limited value.

Medicaid Programmatic Requirements

AHCA operates the Medicaid program within the parameters set throughout ch. 409, F.S. Periodically, changes to federal regulations and program structure result in operations that are no longer consistent with statutory language. The bill includes several provisions updating the statutes to align with current Medicaid practices.

Medicaid Drug Pricing Formulas

Current Situation

Current law outlines formulas to be used by FFS Medicaid when reimbursing pharmacies and other providers of prescription drugs.[22] Providers must be reimbursed at the lowest of the following amounts:

- 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 current law language no longer complies with requirements set by the CMS for the Medicaid program.

[18] S. 409. 915(5)(a), F.S.
[19] S. 409.512(5)(c), F.S.
[20] *Supra* note 9. This includes, for example, women who receive family planning services. Persons with developmental disabilities on the Medicaid iBudget waiver receive full Medicaid benefits, but may choose to enroll in a MMA plan or remain in FFS. *See* Ss. 409.965 and 409.972 for a complete list of individuals who are not required to enroll in an MMA plan, but may do so voluntarily.
[21] *Supra* note 12.
[22] Ss. 409.908(14) and 409,912(5), F.S.

On February 1, 2016, the CMS published a final regulation modifying the reimbursement parameters for state Medicaid programs.[23] The regulation, which required compliance by states beginning in April 2017, required each state Medicaid program to reimburse providers of prescribed drugs at an aggregate upper limit based on the actual acquisition cost of a drug plus a dispensing fee established by the state Medicaid agency.[24]

In response to the federal regulation, AHCA updated its administrative rule detailing the methodology to be used in reimbursing providers of prescribed drugs.[25]

Current law also requires AHCA to implement a variable dispensing fee for prescribed drugs reimbursed under the FFS Medicaid program. The variable dispensing fee encourages pharmacies to fill prescriptions using products on the preferred drug list whenever possible. However, CMS regulations finalized in 2017 established the requirement for a "professional dispensing fee" associated with FFS Medicaid drug reimbursements.[26] The professional dispensing fee, which compensates for costs beyond the ingredient cost of a covered outpatient drug, is provided at the point of sale or service each time a covered outpatient drug is dispensed. The CMS requirement for a professional dispensing fee conflicts with the Florida law requiring a variable dispensing fee.

Effect of the Bill – Medicaid Drug Pricing Formulas

The bill eliminates language outlining the drug reimbursement formulas that were used by AHCA for FFS drug reimbursement prior to the 2016 change in federal Medicaid regulations. The bill specifies that providers of prescribed drugs in the Medicaid program shall be reimbursed an amount not exceeding the lesser of:

- The actual acquisition cost of a drug based on CMS pricing files plus a professional dispensing fee;
- The wholesale acquisition cost of a drug 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 for a drug.[27]

This revised set of FFS reimbursement benchmarks complies with revised federal Medicaid regulations and matches the formulas outlined in AHCA's administrative rule.

The bill deletes the requirement for a variable dispensing fee under FFS Medicaid, which is rendered obsolete by the 2017 CMS regulations. AHCA is in compliance with the federal regulations, so the elimination of the variable dispensing fee reflects current agency practice.

Drug Safety Warnings

Current Situation

The United States Food and Drug Administration (FDA) is responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.[28] The FDA

[23] Medicaid Program; Covered Outpatient Drugs, 81 FR 5169 (February 1, 2016)(codified at 42 CFR Part 447).
[24] 42 CFR Parts 447.512 and 447.514.
[25] Rule 59G-4.251, F.A.C.
[26] *Supra* note 24.
[27] There are numerous different models and metrics used to determine the price of prescribed drugs. For more information, see *US Pharm*. 2012;37(6)(Generic Drug Review suppl):40-45. https://www.uspharmacist.com/article/understanding-drug-pricing (last accessed May 3, 2021).
[28] U.S. Food & Drug Administration, *What We Do*, https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last accessed May 3, 2021).

regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).[29] The FDCA prohibits any drug from being introduced or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated or misbranded drugs and devices from being introduced, delivered for introduction, or received in interstate commerce.

Although the FDA has rigorous processes to screen drugs for safety and efficacy, some safety problems surface only after a drug has been on the market and has been used in a broader population. On occasion, the FDA may issue a "black box warning" indicating that a drug may pose serious or life-threatening risks to certain individuals. In rare cases, FDA may need to reassess the availability of a drug.[30]

The Medicaid Pharmacy and Therapeutics (P&T) Committee is responsible for advising AHCA on the clinical efficacy, safety, and cost-effectiveness of prescribed drugs. The P&T Committee was established to assist AHCA in the development and maintenance of a preferred drug list. The Committee includes medical practitioners and pharmacists and generally meets quarterly to consider revisions to the Medicaid preferred drug list.[31]

Current law specifies that the P&T Committee must review specific actions taken by the FDA at their next regularly scheduled meeting. This includes any "black box warnings" issued by FDA or actions by a drug manufacturer to remove a drug from distribution.[32] In practice, however, such warnings and actions require immediate action by AHCA. If a drug is removed from distribution for safety reasons, AHCA makes immediate changes to pharmacy reimbursement systems to ensure that pharmacy claims for that drug are not approved. When FDA mandates a black box warning, AHCA immediately updates the clinical criteria for those drugs.[33]

Effect of the Bill – Drug Safety Warnings

The bill deletes the review of any drug or class of drugs by the P&T Committee that was the subject of a recent FDA black box warning or removal from distribution by its manufacturer. This change ensures that the Agency can take immediate action when notified of drug safety concerns, without waiting for the next quarterly P&T Committee meeting.

Medicaid Prior Authorization

Current Situation

AHCA is required to respond to requests for "prior consultation" associated with prescribed drugs by telephone or other telecommunication device within 24 hours after receipt of a request.[34]

A consultation as it relates to prescribed drugs is a review of medications with a licensed pharmacist. By reviewing medical history, the drugs prescribed, any over-the-counter medications, and/or herbal or vitamin products being consumed, the pharmacist can provide a wealth of information; they can explain how the medications work and why they are being taken, the best ways to take the medication, the possible side effects to watch for, potential conflicts with other medications or other diseases, and sometimes ways to use medications more economically.

[29] 21 U.S.C. s. 355(a).
[30] U.S. Food & Drug Administration, *A Guide to Drug Safety Terms at FDA*, November 2012. https://www.fda.gov/media/74382/download (last accessed May 3, 2021).
[31] S. 409.91195, F.S.
[32] S. 409.91195(9), F.S.
[33] *Supra* note 12.
[34] S. 409.912(5)(a), F.S.

However, neither AHCA nor the Medicaid managed care plans provide consultations, as that responsibility lies with pharmacies and pharmacists.[35] This statutory provision appears to be an inaccurate use of a term of art.

AHCA and the managed care plans do, however, provide "prior authorization" for certain prescribed drugs and medical services. Prior authorization is a process whereby a provider, on behalf of a patient, must request approval or authorization from the health plan before delivering a treatment or service in order for the treatment or service to be covered by the health plan.[36] In some cases, the use of prior authorization and other medical management techniques can serve as a deterrent to inappropriate care. In the context of prescribed drugs, prior authorization is often used to ensure that a patient is provided with medications that are both cost-effective and appropriate for each patient.[37]

Effect of the Bill – Medicaid Prior Authorization

The bill replaces the term "consultation" with the term "authorization" in s. 409.912(5)(a), F.S. This change reflects agency practice in FFS Medicaid, the practices of the MMA plans, and is consistent with terminology used by other entities in the health care system.

Home Delivery of Prescribed Drugs

Current Situation

Current law requires AHCA to expand home delivery of pharmacy products. In 2010, the Legislature directed the AHCA, through specific proviso language,[38] to issue an invitation to negotiate with a pharmacy or pharmacies to provide mail order delivery services at no cost to the patients who elect to receive their drugs by mail order delivery services for patients with chronic diseases. The following year, the Legislature directed AHCA to implement a mail-order pharmacy program with a focus on serving recipients with chronic diseases.[39]

These home delivery expansions occurred prior to the establishment of the MMA program. Under MMA, each participating health plan manages its own pharmacy network, including mail-order pharmacy.[40] FFS Medicaid also covers prescribed drugs via mail-order, provided that certain conditions are met.[41] Accordingly, the Agency has complied with the current law directive to expand home delivery of pharmacy products.

Effect of the Bill – Home Delivery of Prescribed Drugs

The bill deletes the direction to expand home delivery of pharmacy products. Current programs available to both MMA and FFS Medicaid recipients fulfill the purpose of the statute.

[35] *Supra* note 12.
[36] America's Health Insurance Plans, *Frequently Asked Questions: Medical Management and Prior Authorization*, https://www.ahip.org/wp-content/uploads/Prior-Authorization-FAQs.pdf (last accessed May 3, 2021).
[37] *Id*.
[38] Specific Appropriation 205, Ch. 2010-152, L.O.F.
[39] Ch. 2011-61, L.O.F.
[40] Agency for Health Care Administration, *2018-2023 Model Health Plan Contract: Exhibit II-A – Managed Medical Assistance Program*, October 1, 2020, https://ahca.myflorida.com/medicaid/statewide_mc/model_health_FY18-23.shtml (last accessed May 3, 2021).
[41] Agency for Health Care Administration, *Prescribed Drugs Services Coverage Policy*, December 2017, https://ahca.myflorida.com/medicaid/review/Specific/59G-4.250_Prescribed_Drug_Coverage_Policy.pdf (last accessed May 3, 2021).

Drugs for Erectile Dysfunction

Current Situation

AHCA must limit coverage of a drug prescribed to treat erectile dysfunction[42] to one dose per month.[43] This requirement has been superseded by federal law restricting Medicaid coverage of such drugs.[44] The CMS confirmed that drugs treating erectile dysfunction would not be subject to federal financial participation under Medicaid in a letter to state Medicaid Directors on December 29, 2005.[45] The letter clarified that such drugs would only be eligible for Medicaid coverage in cases where the drug is used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.[46]

Effect of the Bill – Drugs for Erectile Dysfunction

The bill deletes current law limiting coverage of drugs prescribed for erectile dysfunction.

Medicaid Fair Hearings

Current Situation

Pursuant to federal law, AHCA must have a system to conduct fair hearings for Medicaid enrollees whose Medicaid services are denied, suspended or reduced.[47] Under the MMA program, participating health plans conduct these hearings, but AHCA is responsible for conducting hearings for the FFS population. Until 2016, the Office of Fair Hearings within the Department of Children and Families (DCF) administered these hearings on behalf of AHCA. The 2016 legislation moved the administration of Medicaid service-related fair hearings from DCF to AHCA.[48]

Current law retains a reference to fair hearing processes administered by DCF. In the section of law outlining the duties of the Medicaid P&T Committee, Medicaid recipients are provided the right to appeal preferred drug formulary decisions using the Medicaid fair hearing process administered by DCF.[49]

Effect of the Bill – Medicaid Fair Hearings

The bill corrects current law to indicate that preferred drug formulary decisions made by AHCA may be appealed using the Medicaid fair hearing process administered by AHCA. This is consistent with the previous transfer of this function from DCF to AHCA.

Medical Necessity Determinations

Current Situation

AHCA is responsible for overseeing the integrity of the Medicaid program, to prevent and minimize fraudulent and abusive billing, and to recover overpayments and impose sanctions as appropriate. AHCA's Office of Medicaid Program Integrity reviews anti-fraud plans for all participating Medicaid

[42] *See* Mayo Clinic, *Erectile Dysfunction*, https://www.mayoclinic.org/diseases-conditions/erectile-dysfunction/symptoms-causes/syc-20355776 (last accessed May 3, 2021).
[43] S. 409.912(5)(a)9., F.S.
[44] 42 USC 1396r–8(d)(2)(K).
[45] Centers for Medicare and Medicaid Services, *State Medicaid Director Letter #05-006*, December 29, 2005, https://www.medicaid.gov/federal-policy-guidance/downloads/SMD122905.pdf (last accessed May 3, 2021).
[46] Sildenafil (Viagra) is one example. The drug was initially approved by the FDA for treatment of erectile dysfunction, but has since been approved for the treatment of pulmonary hypertension.
[47] *See* 42 CFR parts 431 and 438.
[48] Ch. 2016-65, L.O.F.
[49] S. 409.91195(11), F.S.

health plans.[50] As part of the larger program integrity provisions, health care providers are required to demonstrate the medical necessity of services delivered under the Medicaid program.[51]

Health care services are deemed "medically necessary" when they ease the effects of a terminal condition, or prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain, or results in illness. Such services must also be provided in accordance with accepted standards of medical practice.[52] Medicaid goods or services are excessive or not medically necessary unless both the medical basis and the specific need for them are fully and properly documented in the recipient's medical record.

Determinations of medical necessity must be made by a licensed physician employed by or under contract with AHCA.[53] However, federal Medicaid regulations allow for other licensed practitioners, such as an advanced practice registered nurse or certified behavior analyst, to make medical necessity determinations when acting within their scope of practice.[54]

Effect of the Bill – Medical Necessity Determinations

The bill gives AHCA the flexibility to use doctoral-level certified behavior analysts for medical necessity determinations, when appropriate. Physicians may also make medical necessity determinations for behavior analysis services, and will continue to make all other medical necessity determinations. Such determinations will be made based on the information available at the time services are requested, rather than when the services are provided. This change brings Florida law into alignment with federal Medicaid regulations allowing for medical necessity determinations to be made by specialized medical practitioners under certain circumstances.

Organ Transplant Advisory Council

Current Situation

The Organ Transplant Advisory Council (OTAC) was created in 1986 to recommend to AHCA indications for adult and pediatric organ transplants, to formulate guidelines and standards for organ transplants, and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs.[55] The Council consists of twelve active transplant physicians/surgeons. The recommendations, guidelines, and standards developed by OTAC are applicable only to those health programs funded through AHCA.[56]

According to AHCA, the duties and responsibilities of OTAC have become obsolete because OTAC predates the current oversight of organ transplant services by CMS,[57] as well as multiple other organizations that establish the standard of care for organ transplants.[58] The last OTAC meeting was on April 14, 2015.[59]

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[50] S. 409.913, F.S.
[51] S. 409.913(7), F.S.
[52] S. 409.913(1)(d), F.S.
[53] *Id.*
[54] *See*, for example, CFR 42 Part 440.130 or 42 CFR Part 440.230(d).
[55] Ch. 86-208, ss. 1,2, L.O.F.; S. 765.53, F.S.
[56] S. 765.53(6), F.S.
[57] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Federal Register/Vol. 72, No. 61/Friday, March 30, 2007, available at https://ahca.myflorida.com/medicaid/organ_transplant/pdfs/federal_register_final_rule_for_organ_transplants.pdf (last accessed May 3, 2021).
[58] *Supra* note 12. The other organizations that establish the standard of care include: the Organ Procurement and Transplantation Network; the Health Resources and Services Administration within the U.S. Department of Health & Human Services; the United Network for Organ Sharing; the Foundation for the Accreditation of Cellular Therapy; the Joint Commission; and the International Society for Heart and Lung Transplantation.
[59] Agency for Health Care Administration, Organ Transplant Advisory Council Meeting Information, Meeting Minutes, available at https://ahca.myflorida.com/Medicaid/organ_transplant/meetings.shtml (last accessed May 3, 2021).

Effect of the Bill – Organ Transplant Advisory Council

The bill eliminates the Organ Transplant Advisory Council. This change does not impact Medicaid recipients or providers, as AHCA relies on other guidance for organ transplant services.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.