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BioFlorida – State Legislative Report

July 1, 2025

Overview

"May and June is a lovely time to be in Tallahassee, and we all look forward to being here." That was the quote from Senate Appropriations Chair Ed Hooper after announcing the need for more time to pass the state budget. On Friday, May 2, the Legislature concluded its policy work after horse-trading on the remaining priorities of each chamber. Although work on substantive legislation concluded, the 2025 Legislative Session did not. On the scheduled final day of the legislative session, legislators extended it to June 6.

On June 5, the session was extended again to June 18 due to continued differences between the two chambers on the budget and the tax relief package. The session finally concluded just before 11:30 pm on June 16 (the 105th day of the 60-day session) after legislators approved the $115.1 billion 2025-26 state budget and adjourned sine die.

2025-26 Budget

The approved budget (SB 2500) represents a $3.8 billion reduction from the previous year's budget and a decrease in the size of the state government by nearly 2,000 positions. The budget retains $12.4 billion in total reserves, $4.9 billion in the Budget Stabilization Fund (BSF), and $500 million in the Emergency Preparedness and Response Fund. On June 30, Governor DeSantis signed the $117.4 billion FY-2025-26 budget into law after issuing $1.35 billion in vetoes.

Two accompanying measures reflecting the agreement between the Senate President and House Speaker to reduce state spending, provide long-term fiscal safeguards, and deliver recurring tax reductions for all Floridians were approved with the budget.

- House Joint Resolution 5019 proposes an amendment to the Florida Constitution for the 2026 ballot, increasing the amount of funds that may be retained in the BSF from the current 10 percent to 25 percent of General Revenue collections. The proposed amendment requires an annual transfer of $750 million to the BSF until the cap is reached.

- House Bill 5017 creates a state Debt Reduction Program by providing a recurring $250 million transfer from General Revenue to accelerate the early retirement of outstanding state bonds.

New Budget Trend. Before the 2025 Session commenced, the House Speaker and Senate President agreed that a better understanding of how the state funds are spent was needed to make future funding decisions. The result was a higher-than-usual amount of proviso language in the budget, which increased agency reporting on programs and spending to the Governor and Legislature. Attached is a document outlining the required reports and communications from state agencies that may be of interest to BioFlorida members.

Tax Relief

The tax relief package (HB 7031) provides $1.29 billion in tax relief, including the elimination of the business rent tax and broad-based tax relief opportunities for Florida families and seniors (Tax Relief Package). The Governor signed the bill on June 30, and it takes effect July 1, 2025.

The bill eliminates the business rent tax effective October 1, 2025. It also requires a study by the Office of Economic and Demographic Research (EDR) on the state's property tax system, with a report to the Legislature due by November 1, 2025. Other provisions include:

- Creates the Home Away from Home Tax Credit ($13 million), which allows Florida businesses to receive a tax credit for contributing to charitable organizations that provide housing for families of critically ill children while they are traveling.

- Creates the Rural Communities Investment Program, which allows investors to earn a total of $7 million in annual tax credits against corporate income or insurance premium tax by investing in a rural fund.

- Allows counties and school boards to reduce or repeal certain local discretionary sales surtaxes in effect by a two-thirds vote.

- Extends the freeze on the rate increase for local communications services taxes (CST) from January 1, 2026, to January 1, 2031.

- Makes permanent the Back-to-School Sales Tax Holiday for the month of August.

- Creates a hunting, fishing, and camping sales tax holiday from September 8 to December 31, 2025.

- Exempts permanently from sales tax: AA-cell, AAA-cell, C-cell, D-cell, 6-volt, or 9-volt batteries; fire extinguishers, smoke detectors or smoke alarms, and carbon monoxide detectors; certain portable generators, waterproof tarpaulins and flexible waterproof sheeting 1,000 square feet or less, ground anchor systems and tie-down kits, five-gallon or less gas or diesel fuel cans; bicycle helmets; sunscreen, insect repellent, and life jackets; and admission to Florida State Parks.

- Exempts charitable trusts from the Corporate Income Tax.

Policy Issues Approved by the Legislature (alphabetically)

Department of Health | HB 1299 by Rep. Taylor Yarkosky (R-Clermont) | The legislative package for the Department of Health (DOH) amends statutes related to vaccine definitions, healthcare provider licensure qualifications, and medical marijuana treatment center (MMTCs) reporting. Specific provisions include:

- Postponing from 2025 to 2027 the scheduled repeal of the statutory definition of "messenger ribonucleic acid vaccine."

- Re-enacting provisions related to discrimination and the prohibition of mask or vaccination mandates.

- Changing the required timeframe for active practice for licensure by endorsement from three years to two years under the Mobile Opportunity by Interstate Licensure Endorsement Act.

- Requiring additional reporting of medical marijuana treatment centers and medical marijuana testing laboratories.

- Adding the Orlando College of Osteopathic Medicine and Lincoln Memorial University to the list of institutions eligible for medical faculty certificates. These certificates allow physicians who hold full-time faculty positions at eligible schools to practice medicine in Florida without the prerequisite of sitting for and successfully passing a national examination.

- Narrowing the eligibility criteria for physician assistants (PAs) seeking to practice under a temporary certificate to practice in areas of critical need. The PA must be licensed in a U.S. state or the District of Columbia, and excludes PAs licensed in other U.S. jurisdictions, such as Puerto Rico or Guam.

- Requiring Medical Marijuana Treatment Centers (MMTCs) to report theft, loss, or diversion of medical marijuana, actual or attempted, to the DOH in addition to local law enforcement.

The Governor signed the bill on June 2, and it takes effect July 1, 2025.

Diagnostic and Supplemental Breast Exam Coverage | SB 158 by Sen. Lori Berman (D-Boynton Beach) | The bill prohibits the state group insurance program from imposing cost-sharing for diagnostic breast and supplemental breast exams in a contract or plan for state employee health benefits, providing coverage for diagnostic and supplemental breast exams. The prohibition takes effect on January 1, 2026, coinciding with the start of the new plan year.

The Governor signed the bill on May 20, and it takes effect January 1, 2026.

Employment Agreements | HB 1219 by Rep. Traci Koster (R-Safety Harbor) | The bill attempts to counterbalance a recent ruling being challenged by the Federal Trade Commission, which banned noncompete agreements nationwide. The bill establishes the framework for using covered garden leave agreements and covered noncompete agreements between a covered employer and a covered employee. It also:

- Requires employees to be given seven days to review these agreements before signing.

- Limits the duration of the agreements to a maximum of four years.

- Defines "covered employee" as someone earning more than twice the annual mean wage in the county where they work or reside, excluding medical professionals.

The bill was delivered to the Governor on June 18. If approved, it takes effect July 1, 2025.

Foreign Countries of Concern | SB 768 by Sen. Calatayud (R-Miami) | The bill requires healthcare licensees to meet new controlling interest requirements to limit ties to foreign countries of concern. Specifically, the bill:

- Requires healthcare providers, as a condition of licensure, to ensure that a person or entity with a direct controlling interest in the healthcare provider does not directly hold an interest

in an entity with a business relationship with a foreign country of concern or is subject to the statute prohibiting contracting with scrutinized companies.

- Prohibits the clinical and environmental laboratories run by the Bureau of Public Health Laboratories within the Department of Health from using genetic sequencing software produced in or by a foreign country of concern, a state-owned enterprise of a foreign country of concern, or a company domiciled within a foreign country of concern.

- Provides that foreign countries of concern include China, Russia, Iran, North Korea, Cuba, the Venezuelan regime of Nicolas Maduro, and Syria. Scrutinized companies may include those that boycott Israel or have prohibited operations in Cuba, Iran, Sudan, or Syria.

The Governor signed the bill on May 27, and it takes effect July 1, 2025.

Health Care Conforming Legislation | SB 2514 by Appropriations | Conforming legislation amends the Florida Statutes to provide for specific provisions in the budget bill. The bill contained the following provisions:

Cancer Research Provisions

Definitions

- Redefines "cancer center" as a comprehensive center with at least one geographic site in the state, a freestanding center located in the state, a center situated within an academic institution, or a Florida-based formal research-based consortium under centralized leadership that has achieved NCI designation.

- Redefines "Florida based" as a cancer center's actual or sought designated status is or will be recognized by the NCI as primarily located in Florida, or that a healthcare provider or facility is physically located in and provides services in Florida.

Cancer Innovation Fund

- Establishes eligibility criteria for grants and prioritizes projects that expand screening in underserved areas.

- Requires a Report to the Governor and the Legislature by December 1, 2025, and annually thereafter.

Cancer Connect Collaborative Research Incubator

- Creates the incubator to provide funding for pediatric cancer research over a five-year period, beginning July 1, 2025.

- Authorizes funding in the Casey DeSantis Research Program for cancer centers accredited as a Comprehensive Community Cancer Program or an Integrated Network Cancer Program.

Other Provisions

Bankhead-Coley Program

- Establishes, within the Bankhead-Coley program, the Bascom Palmer Eye Institute VisionGen Initiative to advance genetic and epigenetic research on inherited eye diseases and ocular oncology.

Biomarker Testing

- Requires Statewide Medicaid Managed Care (SMMC) plans to cover medically necessary biomarker testing consistent with the state plan, establish authorization procedures, and

require coverage of blood-based biomarker tests for colorectal cancer screening as specified in federal Medicare determinations.

The Governor signed the bill on June 30, and it takes effect July 1, 2025.

Newborn Screening | HB 1089 by Rep. Erika Booth (R-Orlando) | The bill requires every Florida newborn to be tested for conditions listed on the federal Recommended Uniform Screening Panel, as advised by the Genetics and Newborn Screening Advisory Council. It also requires the Department of Health (DOH) rules, by January 1, 2027, to incorporate testing for Duchenne muscular dystrophy as part of the state's newborn screening protocol.

The Governor signed the bill on May 20, and it takes effect July 1, 2025.

Parkinson's Disease Research | HB 1545 by Rep Demi Busatta (R-Coral Gables) | The bill establishes the Parkinson's Disease Research Consortium at the University of South Florida to conduct and coordinate rigorous scientific research. The bill also:

- Establishes the Parkinson's Disease Research Board to oversee the consortium's operations, develop an annual research plan, and submit annual reports to the Governor and Legislature.

- Establishes the Florida Institute for Parkinson's Disease as a statewide resource dedicated to finding a cure for Parkinson's disease and enhancing patient outcomes through research, clinical care, education, and advocacy.

The Governor signed the bill on June 25, and it takes effect July 1, 2025.

Pediatric Cancer Awareness Month | HB 8041 by Rep. Rita Harris (D-Orlando) | Designates September 2025 as "Pediatric Cancer Awareness Month.

Pediatric Rare Disease Institute and the Sunshine Genetics Consortium | HB 907 by Rep. Adam Anderson (R-Tarpon Springs) | The bill establishes the Florida Institute for Pediatric Rare Diseases within the Florida State University College of Medicine as a statewide resource for research and clinical care related to pediatric rare diseases. It also:

- Requires the Institute to establish and administer the Sunshine Genetics Pilot Program for five years, offering opt-in newborn genetic screening, including whole-genome sequencing. Require the clinical findings from screenings to be released to parents and the newborn's healthcare practitioner.

- Establishes the Sunshine Genetics Consortium to facilitate collaboration among researchers, geneticists, and physicians from Florida universities and children's hospitals.

The Governor signed the bill on June 25, and it takes effect July 1, 2025.

Rare Disease Day - 2025 | HB 8079 by Rep. Adam Anderson (R-Tarpon Springs) | Recognizes February 28, 2025, in Florida as Rare Disease Day to promote awareness of rare diseases and the need for continued research and treatment options. It also:

- Acknowledges the prevalence of rare diseases, affecting nearly one in ten Americans, many of whom are children.

- Highlights the challenges faced by individuals and families with rare conditions, such as diagnosis delays and limited treatment options.

- Encourages continued support and innovation in developing treatments and cures for rare diseases.

- Recognizes the positive impact of the Orphan Drug Act and state-level efforts, such as Florida's Rare Disease Advisory Council.

Stem Cell Therapy | SB 1768 by Sen. Jay Trumbull (R-Panama City) | The bill authorizes licensed physicians working to perform stem cell therapies not approved by the U.S. Food and Drug Administration (FDA) for use in orthopedics, wound care, and pain management. It also:

- Establishes the type of stem cells that can be used and the types of facilities from which a physician may obtain them.

- Requires physicians to provide notice and informed consent to patients receiving the therapies.

- Provides a more detailed definition of "human cells, tissues, or cellular or tissue-based products" to include various biologics from U.S. residents intended for medical use.

- Prohibits use of stem cells from aborted fetuses and defines "human cells, tissues, or cellular or tissue-based products" with specific exclusions such as vascularized organs and minimally manipulated bone marrow.

- Requires stem cells to be from facilities adhering to FDA guidelines and mandates inclusion of post-thaw viability analysis of the stem cells prior to use.

- Exempts certain physicians involved in approved investigational new drug or device studies from the bill's provisions.

- Imposes penalties for illegal stem cell practices, including unauthorized manufacture or distribution.

The Governor signed the bill on June 25, and it takes effect July 1, 2025.

Policy Issues Not Approved by the Legislature *(alphabetically)*

340B Entities and Drugs | HB 1527 by Rep. Gallop Franklin (D-Tallahassee) | The bill sought to establish regulations against discriminatory practices involving 340B drugs and entities. Specifically, the bill:

- Prohibited manufacturers from interfering with the acquisition of 340B drugs by pharmacies contracted by 340B entities, except if restricted by the U.S. Department of Health and Human Services.

- Defined restricted actions for insurers and pharmacy benefit managers (PBMs) concerning the reimbursement rates and contractual conditions for 340B drugs.

- Required that 340B drugs be treated equivalently to other drugs within insurance and benefit structures without undue burdens placed on the 340B entities.

- Stipulated that each violation constitutes an offense under the Florida Deceptive and Unfair Trade Practices Act.

The bill did not receive a hearing this session, and a Senate companion was not filed.

Chemicals in Consumer Products | SB 196 by Sen. Joe Gruters (R-Sarasota) and SB 525 by Rep. Monique Miller (R-Palm Bay) | The bills established labeling requirements for specific food products containing "vaccine or vaccine material" and broadened the definition of "drug" to include those food items. They also provided that any food product containing a vaccine or vaccine material without required labeling is a misbranded drug.

The Senate measure was expanded to prohibit the intentional addition of certain toxic chemicals to cosmetics manufactured, sold, offered for sale, or distributed for sale in Florida. The Senate bill was approved by the Senate; however, the House measure did not receive a hearing.

Clinical Laboratory Personnel | SB 115 by Rep. Ryan Chamberlin (R-Ocala) and 380 by Sen. Stan McClain (R-Ocala) | The bills sought to streamline licensure requirements and processes for clinical laboratory personnel in Florida. The bills:

- Removed the responsibility for the Department of Health (DOH) to conduct exams for clinical laboratory personnel licensure.

- Eliminated the registration of clinical laboratory trainees and repealed the section of law requiring approval of laboratory personnel training programs.

- Provided that applicants meeting federal criteria are deemed to have satisfied state minimum qualifications for licensure as technologists or technicians.

The House measure was heard in one committee; however, the Senate bill did not receive a hearing.

Colorectal Cancer Screening and Diagnosis | HB 1335 by Rep. Karen Gonzalez-Pittman (R-Tampa) and SB 1542 by Sen. Jay Trumbull (R-Panama City) | The bills authorized Medicaid to cover medically necessary blood-based biomarker tests for colorectal cancer screening, sunsetting the required coverage on July 1, 2031.

The Agency for Health Care Administration (AHCA) would have been required to contract for a five-year comparative analysis study calculating the return on investment for the state in covering blood-based biomarker tests for colorectal cancer screening.

The House measure moved through two committees; however, the Senate companion did not receive a hearing. However, language was included in the healthcare conforming bill (SB 2514) requiring Statewide Medicaid Managed Care (SMMC) plans to cover medically necessary biomarker testing consistent with the state plan, establish authorization procedures, and provide coverage of blood-based biomarker tests for colorectal cancer screening as specified in federal Medicare determinations.

Compounding Pharmacies | SB 632 by Sen. Jonathan Martin (R-Ft. Myers) and HB 1407 by Rep. Jenna Persons-Mulicka (R-Ft. Myers) | The bills sought to define and support the rights of chronically and terminally ill patients in Florida to choose their treatment courses, involving individualized

medications compounded by specially-licensed pharmacies. The bills also included the following provisions:

- Defined "chronically ill patient" and “compounding pharmacy".
- Allowed chronically and terminally ill patients to decide on their treatment plans with their health care providers using specialized drugs from a compounding pharmacy.
- Allowed compounding pharmacies to acquire active pharmaceutical ingredients not in the U.S Pharmacopeia if obtained from registered manufacturers and delivered with a proper certificate of analysis.
- Specified conditions under which active ingredients removed from the market for safety reasons may not be used and allowed use of substances listed in the Interim 503A Category 2 or 3 Bulk Drug Substances List if they comply with the section's standards.

Neither bill received a hearing.

Continuous Glucose Monitors/Medicaid | SB 1182 by Sen. Gayle Harrell (R-Stuart) and HB 1465 by Rep. Gallup Franklin (D-Tallahassee) | The bills sought to require the Agency for Health Care Administration (AHCA) to seek federal approval to cover continuous glucose monitors and related supplies. The bills also:

- Provided that licensed durable medical equipment providers are reimbursed for continuous glucose monitors and related supplies, using an active Medicare Healthcare Common Procedure Coding System for claim submissions without a National Drug Code number.
- Permitted flexibility for AHCA to offer extra coverage for continuous glucose monitors as a Medicaid pharmacy benefit.

Both bills were heard in committee but did not reach the floor of the House or the Senate.

Ephedrine and Related Compounds Recordkeeping System Fees | HB 237 by Rep. Danny Nix (R-Port Charlotte) and SB 640 by Sen. Jonathan Martin (R-Ft. Myers) | The bills sought to require manufacturers of ephedrine or related compounds to pay a monthly fee to support the operation of the electronic recordkeeping system starting July 1, 2025. The bills would have required manufacturers to provide written proof of fee payment upon request by the Department of Law Enforcement. Neither bill received a hearing.

Mammograms and Supplemental Breast Cancer Screening | SB 1578 by Sen. Traci Davis (D-Jacksonville) and HB 187 by Rep. Dianne Hart (D-Tampa) | The bills sought to require coverage for one annual mammogram and one supplemental screening under certain conditions such as dense breast tissue or increased cancer risk due to personal or family history, genetic factors, or other medical reasons as determined by a healthcare provider. The bills also:

- Defined "mammogram" as a radiologic examination intended to detect early-stage breast cancer, specifying the inclusion of both traditional and digital breast tomosynthesis mammograms.
- Introduced "supplemental breast cancer screening" to include additional medically necessary exams such as MRIs, ultrasounds, or molecular breast imaging, following American College of Radiology guidelines.

- Required the Agency for Health Care Administration (AHCA) to seek federal approval if necessary to implement the provisions.

The Senate bill completed the committee process but was not brought to the Senate floor for a vote. The House measure did not receive a hearing.

Medicaid Pharmacy Discounted Drug Prices | HB 657 by Rep. Shane Abbott (R-Marianna) and SB 1064 by Sen. Jay Collins (R-Tampa) | The House bill would have required drug manufacturers to sell drugs listed on the Medicaid preferred drug list and covered under the 340B Program at discounted prices. It also would have:

- Allowed manufacturers to deliver drugs using existing methods while mandating rebates if the 340B price exceeds the state-negotiated Medicaid price.

- Mandated pharmacy benefits managers to pay Medicaid pharmacies the 340B discounted price plus a dispensing fee for eligible drugs.

- Required drug wholesalers and distributors to sell eligible drugs to Medicaid pharmacies at 340B discounted prices and prohibited altering current pricing models in ways that would exempt such drugs.

- Restricted Medicaid pharmacies from providing 340B discounted drugs only to Medicaid recipients.

The Senate measure sought to require the Agency for Health Care Administration (AHCA) to conduct a fiscal impact study assessing the implementation of discounted drug prices under the 340B Drug Pricing Program in Medicaid. Neither bill received a hearing this session.

Provenance of Digital Content | HB 369 by Rep. Fiona McFarland (R-Sarasota) and SB 702 by Sen. Danny Burgess (R-Zephyrhills) | The bills sought to create a new section of law related to provenance data of digital content and establish definitions, including "generative artificial intelligence." The bills:

- Required generative artificial intelligence developers to:
  - Make available a provenance application tool that enables the user to apply provenance data, either directly or through the use of third-party technology, to content that has been generated or modified to include synthetic content when such content is generated or modified using the developer's generative artificial intelligence tool; or

  - Use provenance data in a way that is technically feasible and reasonable based on current industry standards, either directly or via third-party technology, for content that has been generated or modified to include synthetic elements.

- Required a social media platform to retain all available provenance data of content uploaded to or posted on the platform and make it available in a readable format to the platform's users directly, through a conspicuous indicator that allows a user to access the provenance data, or both. This does not apply in cases of the user's removal of the data.

- Provided that a violation of the law constitutes an unfair or deceptive act or practice.

- Clarified that the legislation would not apply to any product, service, internet website, or application that exclusively provides video game experiences.

Both bills moved through the committee process but did not reach the House or Senate floor.

Prescription Drug Wholesale Drug Distributor | HB 1461 by Rep. Taylor Yarkosky (R-Clermont) and SB 1452 by Sen. Keith Truenow (R-Tavares) | These bills sought to repeal certain boards, councils, and commissions under the Department of Business and Professional Regulation (DBPR) and the Department of Agriculture and Consumer Services (DACS). They would also have repealed the continuing education requirements for certain licensed professionals.

Specifically, the bills would have abolished the Drug Wholesale Distributor Advisory Council, which is responsible for reviewing the Florida Drug and Cosmetic Act, adopting rules, and advising DBPR on improving coordination with other states' regulatory agencies and the federal government. The bills also would have eliminated the requirement that each prescription drug wholesale distributor must have at least one designated representative certified by the department.

The House bill advanced through the committee process; however, the Senate measure did not get a hearing. Near the end of the session, the House included the language in a Senate President priority bill (SB 110). However, the measure ultimately did not receive final approval.

Research and Development Tax Credit | SB 1244 by Sen. Alexis Calatayud (R-Miami) and SB 1377 by Rep. Leonard Spencer (R-Winter Garden) | The bills would have increased the annual cap on tax credits available under the research and development tax credit program from $9 million to $50 million. Neither bill received a hearing.

Step Therapy Protocols for Mental Health Drugs | SB 264 Sen. Gayle Harrell (R-Stuart) and HB 721 by Rep. Karen Gonzalez-Pittman (R-Tampa) | The bills sought to require the Agency for Health Care Administration (AHCA) to approve certain drugs for the treatment of serious mental illnesses in Medicaid recipients without the need for step-therapy prior authorization. The bills also:

- Identified specific conditions under which a drug product for the treatment of serious mental illness must be approved, including lack of effective alternatives on the preferred drug list, prior ineffectiveness of alternatives, or known ineffectiveness based on historical evidence.

- Allowed for immediate approval if additional medical documentation is provided to show necessity, without waiting for the step-therapy process.

The Senate bill moved through one committee; however, the House measure did not receive a hearing.

Surgical Smoke Protection | HB 103 by Rep. Marie Woodson (D-) and SB 152 by Sen. Traci Davis (D-Jacksonville) | The bills sought to require hospitals and ambulatory surgical centers to adopt and implement policies by January 1, 2026 and require the use of smoke evacuation systems during any surgical procedure likely to generate surgical smoke. The bills also required the systems to capture, filter, and eliminate surgical smoke at the origin site before it makes contact with the eyes or respiratory tract of occupants in the room. The bills moved through the committee process but did not reach the floor of either chamber.

Vaccine and Drugs Claims for Adverse Reactions to under Medicaid & Medically Needy Programs | HB 149 by Rep. Webster Barnaby (R-Deland) and SB 1362 by Sen. Ileana Garcia (R-Miami)

| The bills sought to streamline the Medicaid review and payment process for claims involving severe reactions to certain vaccines and drugs. They also:

- Required the Agency for Health Care Administration (AHCA) to expedite claims evaluations and payments when physicians diagnose severe injuries from vaccines, immunizing agents, or emergency countermeasure drugs recommended by the FDA or the state health department.

- Require AHCA to publish a list of medical conditions and potential severe adverse reactions associated with these vaccines and drugs on its website.

Neither bill received a hearing.

Looking Ahead

The 2026 Legislative Session will begin on Tuesday, January 13th, and is scheduled to end on Friday, March 13th. Interim legislative committee meetings are scheduled for the following weeks:

October 6-10, 2025
October 13-17, 2025
November 3-7, 2025
November 17-21, 2025
December 1- 5, 2025
December 8-12, 2025

Proviso Language in the FY 2025-26 Budget

(SB 2500)

Monthly Reconciliation Report – Agency for Health Care Administration

The Legislature added new language for a monthly reconciliation report, including an accounting for federal revenues. The first report is due September 15th. (Page 64)

> *From the funds in Specific Appropriations 171 through 225, the Agency for Health Care Administration shall provide a monthly reconciliation report for all Grants and Donations Trust Fund and Medical Care Trust Fund expenditures and revenues. The report shall include actual expenditures to date by category and revenue collections to date for each month and shall be reconciled to state accounting records. The report shall provide the specific type and source of any revenues collected to date, detailing any applicable Catalog of Federal Domestic Assistance/Assistance Listing Number and statutory references related to the specific revenue collected. The report shall specify each expenditure to date, detailing the specific revenue type and revenue source utilized to pay each expenditure, and the applicable Catalog of Federal Domestic Assistance/Assistance Listing Number and statutory reference related to the specific revenue. The report shall also include the cash balance of the trust fund to date, detailing each revenue source that comprises the fund balance, and the applicable Catalog of Federal Domestic Assistance/Assistance Listing Number and statutory reference related to each revenue source. The report shall be provided to the chair of the Senate Appropriations Committee and the chair of the House of Representatives Budget Committee by the 15th day of the month following the reporting month. The agency must submit the first report by September 15, 2025.*

Financial Data Sharing Agreement – Agency for Health Care Administration

The Legislature required AHCA to enter into a financial sharing agreement with OPPAGA by September 1st. (Page 64-65)

> *From the funds in Specific Appropriations 171 through 225, the Agency for Health Care Administration shall enter into a single Medicaid financial data sharing agreement with the Office of Program Policy Analysis and Government Accountability (OPPAGA) and the vendor it selects by September 1, 2025. The vendor selected by OPPAGA shall include an actuary who is not associated with the Florida Medicaid Program or any Medicaid managed care organization that is currently contracting with the state of Florida.*
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> *The data sharing agreement shall include, but not be limited to, Medicaid eligibility data, Medicaid claims data, Achieved Savings Rebate financial data submissions, Florida Medicaid Management Information System encounter data and other supporting information from the agency and the Statewide Medicaid Managed Care plans. The agreement shall include the underlying data relied upon by the agency and the contracted actuary in their development of the Medicaid capitation rates, including, but not limited to, data associated with the development of the base data costs, adjustments made to the base data, documents associated with the trend assumption in developing the capitation rates and other supporting information. The data agreement shall be in accordance with industry standard HIPAA and HITECH compliance standards for data and document management.*
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> *The Agency for Health Care Administration shall provide to OPPAGA, the chair of the Senate Appropriations Committee, and the chair of the House of Representatives Budget Committee the following contractually required reports submitted by the Statewide Medicaid Managed*

Care plans to the agency as outlined in the single Medicaid financial data sharing agreement, within 10 days of receipt by the agency:

- Administrative Subcontractors and Affiliates Report
- Annual and Quarterly Reports for Chronic Disease Management
- Denial, Reduction, Termination or Suspension of Services Report
- Performance Improvement Projects (PIP) Quarterly progress reports
- Performance Measures Report and Measure Action Plan
- Provider Complaint Report
- Special Populations Care Coordination Report
- Value Based Purchasing Report

Notification of Federal Communications – Agency for Health Care Administration
The Legislature required AHCA to provide notification of federal notifications. (Page 67)

From the funds in Specific Appropriations 185 through 225, the Agency for Health Care Administration shall provide written notification, including copies of any official communication, to the Governor's Office of Policy and Budget, the chair of the Senate Appropriations Committee, and the chair of the House of Representatives Budget Committee within five business days of receipt of any official federal communications from the Department of Health and Human Services, the federal Centers for Medicare & Medicaid Services, or other subordinate entities regarding: deferrals, disallowances, compliance actions, approvals or denials of requested programmatic changes, funding adjustments, including changes to federal funding levels, grants or waivers, federal audit findings that could impact program funding or compliance, new federal mandates or guidance that may require legislative or budgetary adjustments, and federal legal challenges or settlements that affect the Florida Medicaid Program or the Children's Health Insurance Program (CHIP).

Canadian Prescription Drug Importation Program Report
The Legislature continued the funding for the Canadian Prescription Drug Importation Program. However, they added new reporting language. (Page 68-69)

191 SPECIAL CATEGORIES CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM FROM GRANTS AND DONATIONS TRUST FUND 15,000,000

Funds in Specific Appropriation 191 are provided to facilitate the purchase of prescription drugs pursuant to the parameters of the Canadian Prescription Drug Importation Program as authorized by section 381.02035, Florida Statutes, for use in state programs outlined in section 381.02035(3), Florida Statutes. Funds expended by the Agency for Health Care Administration for prescriptions utilized by clients of those state programs will be reimbursed to the agency by the appropriate state program office. The agency shall submit a quarterly report to the Governor's Office of Policy and Budget, the chair of the Senate Committee on Appropriations, and the chair of the House of Representatives Budget Committee within 30 days after the last business day of the preceding quarter on the status of the program detailing: a list of participating suppliers and importers, the number of unique prescription drugs available under negotiated contracts, and the number of prescriptions dispensed under the program.

Federal Communications Notification – Agency for Health Care Administration
The Legislature added new language requiring AHCA to provide written notice of federal communications on violations of payments and expenditures. (Page 71)

*From the funds in Specific Appropriations 197 through 225, the Agency for Health Care Administration, upon receipt of any official communication from the Department of Health and Human Services, federal Centers for Medicare and Medicaid Services, other subordinate entities regarding unallowable payments or expenditures in violation of the Florida Managed Medical Assistance 1115 waiver's special terms and conditions, which have or may result in a requirement for the state to repay federal funds, shall provide written notification and copies of the official communication, to the Governor's Office of Policy and Budget, the chair of the Senate Appropriations Committee, and the chair of the House of Representatives Budget Committee within three business days of the date of the communication***.***

Analysis of Cell and Gene Therapy Prescription Drug Access – Agency for Health Care Administration
The Legislature agreed to require AHCA to conduct an analysis of prescription drug access for cell and gene therapies for Medicaid recipients. (Page 73)

The Agency for Health Care Administration shall conduct an analysis evaluating options to support access to prescription drugs used in cell and gene therapies for Medicaid recipients with serious and rare disease states, including, but not limited to, Metachromatic Leukodystrophy, Hemophilia, Duchenne Muscular Dystrophy, Sickle Cell Disease, and Spinal Muscular Atrophy.

The analysis must include: a review of current and emerging cell and gene therapies relevant to the Medicaid population, including market availability, United States Food and Drug Administration approval status, and potential future pipeline; an assessment of policy options for coverage and reimbursement, including, but not limited to, direct agency purchase of therapies; enhanced fee-for-service reimbursement mechanisms; supplemental or kick payments to managed care plans for high-cost therapies; and potential carve-out models and their implications; an analysis of the fiscal impact under each option, including potential costs to the state's Medicaid program; effect on drug rebate revenues and implications for Medicaid financing; risk of duplicative payments and administrative costs; and impact to the actuarial soundness of capitation rates and necessary federal Centers for Medicare & Medicaid Services approvals; consideration of managed care program implications, including necessary adjustments to contracts, risk arrangements, and compliance with federal rate setting and approval requirements; a review of other state Medicaid approaches to funding cell and gene therapies, including lessons learned and outcomes; and an evaluation of implementation feasibility by Medicaid enrollment group, including implications for Statewide Medicaid Managed Care participants in the different plan types and fee-for-service populations.

The analysis must identify short- and long-term risks, including fiscal exposure, access implications, and stakeholder considerations, and provide clear, actionable policy recommendations for legislative consideration. The agency shall consult with relevant stakeholders, including contracted health plans, actuaries, pharmaceutical manufacturers, and Medicaid recipients where appropriate. The analysis shall be submitted to the Governor's Office of Policy and Budget, the chair of the Senate Appropriations Committee, and the chair of the House Budget Committee by January 5, 2026.

Review of Implementation of Biomarker Testing
The Legislature agreed to proviso language on Biomarker testing. (Page 73-74)

The Agency for Health Care Administration shall conduct a comprehensive review of the implementation of chapter 2024-249, Laws of Florida. The report must include, at a minimum, gaps in access to biomarker testing and barriers to coverage, along with solutions

for each; billing codes for biomarker tests (including Proprietary Laboratory Analysis codes) covered by other state Medicaid programs and associated costs in both fee-for-service and managed care; the total number of biomarker testing codes billed to Florida Medicaid, including Proprietary Laboratory Analysis; the number of denied claims and reasons for denial in both managed care and fee-for-service; for approved claims, a breakdown of the specific codes approved by fee-for-service and each managed care plan; the average reimbursement amounts for approved biomarker testing codes; the actuarial analysis used to determine any impact on managed care rates for the 2024-2025 year, based on aligning coverage with current law; and any cost savings from biomarker testing, including cases where it avoided more expensive treatments such as chemotherapy. The agency shall submit the report to the Governor's Office of Policy and Budget, the chair of the Senate Appropriations Committee, and the chair of the House of Representatives Budget Committee by January 5, 2026.

Study of Pharmaceutical Cost for Medicaid Drugs – Office of Insurance Regulation

The Legislature provided dollars to OIR to conduct a study of pharmaceutical costs for drugs dispensed under the Florida Medicaid Managed Care Plan. (Page 415-416)

2357 SPECIAL CATEGORIES CONTRACTED SERVICES FROM INSURANCE REGULATORY TRUST FUND 2,813,016

From the funds in Specific Appropriation 2357, $300,000 is provided for the Office of Insurance Regulation to competitively procure a study to examine pharmaceutical costs for drugs dispensed under the Florida Medicaid Managed Care Plan. The study shall consider pharmacy utilization data from the most recent applicable plan year to compare existing pharmaceutical reimbursement costs with other reimbursement methodologies and cost-savings measures that also promote predictability and sustainability for pharmacies located within the state. The study shall include a reimbursement methodology using an amount equal to the National Average Drug Acquisition Cost or if there is no National Average Drug Acquisition Cost for such product, Wholesale Acquisition Cost, plus a professional dispensing fee of $10.24 for Florida Medicaid Managed Care Plan. The office shall submit a report summarizing the results of the study to the President of the Senate, Speaker of the House of Representatives, and the Executive Office of the Governor by June 30, 2026.

Funding for Cell and Gene Therapy

The Legislature agreed to provide $20,000,000 for the purchase of cell and gene therapies for Medicaid children with Metachromatic Leukodystrophy, Hemophilia, Duchenne Muscular Dystrophy, Sickle Cell Disease, and Spinal Muscular Atrophy. (Page 512)

SECTION 78. The nonrecurring sums of $8,526,000 from the General Revenue Fund and $11,474,000 from the Medical Care Trust Fund are provided to the Agency for Health Care Administration in Specific Appropriation 215 of Chapter 2024-231, Laws of Florida, for the purchase of prescription drugs used in cell and gene therapies for children who are Medicaid recipients with Metachromatic Leukodystrophy, Hemophilia, Duchenne Muscular Dystrophy, Sickle Cell Disease, and Spinal Muscular Atrophy. No recalculation of managed care capitation payments will be made based upon these direct purchases by the Agency for Health Care Administration. The unexpended balance of these funds on June 30, 2025, shall revert and is appropriated to the agency for Fiscal Year 2025-2026 for the same purpose.