FLORIDA HOUSE OF REPRESENTATIVES FINAL BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.				
BILL #: <u>HB 5301</u> PCB HCB 25-0	<u>1</u>		COMPANION BILL: <u>SB 2514</u>	
TITLE: Health Care			LINKED BILLS: None	
SPONSOR(S): Andrade			RELATED BILLS: None	
FINAL HOUSE FLOOR ACTION:	105 Y's	0 N's	GOVERNOR'S ACTION:	Approved
SUMMARY				

Effect of the Bill:

HB 5301 passed as SB 2514 on June 16, 2025. The bill conforms statutes to the General Appropriations Act (GAA) for Fiscal Year 2025-2026, making several changes related to Health Care. Specifically, the bill makes changes related to cancer research, medical school loan and funding programs, medical marijuana registration, Medicaid coverage of biomarker cancer screenings, Medicaid enrollment for the permanently disabled, Medicaid financial assistance, Achieved Savings Rebate audit procedures, and regulations regarding the operation of Programs for All-Inclusive Care for the Elderly.

The bill was approved by the Governor on June 30, 2025, ch. 2025-204, L.O.F., and became effective on July 1, 2025.

Fiscal or Economic Impact:

See fiscal impact section.

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<u>ANALYSIS</u>

RELEVANT INFORMATION

ANALYSIS

EFFECT OF THE BILL:

Dental Student Loan Repayment Program

SUMMARY

The bill allows dental students and dental hygiene students who have been offered employment at certain public health programs or private practices to apply for the Dental Student Loan Repayment Program before obtaining active employment; however, funds may not be awarded until the following program requirements are met:

- Demonstrate active employment in a public health program or private practice that serves Medicaid recipients and other low-income patients and is located in a dental health professional shortage area or a medically underserved area.
- Volunteer 25 hours per year, verified by the Department of Health (DOH), providing dental services in a free clinic that is in a dental health professional shortage area or a medically underserved area, through another volunteer program operated by the state pursuant to part IV of chapter 110, or through a probono program approved by the Board of Dentistry. (Section <u>1</u>).

Casey DeSantis Cancer Research Program

Definitions

The bill revises the definition of "Florida-based" to specify that in order for health care providers and facilities to meet the definition, such an entity must be physically located in Florida and provide services in Florida.

The Collaborative

The bill provides that the President of the Senate and the Speaker of the House of Representatives each have three appointments to the membership of the Florida Cancer Connect Collaborative (Collaborative), instead of one apiece as under current law. This results in the Governor and the Legislature's presiding officers each having three appointments.

The bill deletes the obsolete requirement for the Collaborative to develop and submit a long-range comprehensive plan for the Casey DeSantis Program by December 1, 2024.

Cancer Innovation Fund

The bill creates parameters for the awarding of grants through the Cancer Innovation Fund, including:

- A new criterion for applications that will get priority during the Collaborative's review of proposals for grant funding. The new priority criterion will be applications having the goal to expand the reach of cancer screening efforts into underserved areas.
- A list of criteria that grant applicants must meet in order to be eligible. Under the bill, an eligible applicant must:
 - Operate as a licensed hospital that has a minimum of 30 percent of current cancer patients that reside in rural or underserved areas;
 - Operate as a licensed health care clinic or facility that employs or contracts with at least one Florida-licensed allopathic or osteopathic physician who is board-certified in oncology and that delivers chemotherapy treatments for cancer;
 - Operate as a licensed facility that employs or contracts with at least one Florida-licensed allopathic or osteopathic physician who is board-certified in oncology and that delivers radiation therapy treatments for cancer;
 - Operate as a licensed health care clinic or facility that provides cancer screening services at no cost or a minimal cost to patients;
 - Operate as a rural hospital as defined in s. 395.602(2)(b), F.S.;
 - Operate as a critical access hospital as defined in s. 408.07(14), F.S.;
 - Operate as a specialty hospital as defined in s. 395.002(28)(a), F.S., that provides cancer treatment for patients from birth to 18 years old;
 - Operate as a licensed hospital that is accredited by the American College of Surgeons as a Comprehensive Community Cancer Program or Integrated Network Cancer Program.
 - Engage in biomedical research intended to develop therapies, medical pharmaceuticals, treatment protocols, or medical procedures intended to cure cancer or improve the quality of life of cancer patients; or
 - Educate or train students, post-doctoral fellows, or licensed or certified health care practitioners in the screening, diagnosis, or treatment of cancer.
- A requirement to ensurall proposals are appropriate and are evaluated fairly on the basis of scientific merit, the DOH must appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish a priority score. The priority scores must be forwarded to the Collaborative and must be considered in determining which proposals the Collaborative recommends for grant funding. The bill requires members of the Collaborative and the panels to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy regarding conflicts of interest.
- A requirement for the Collaborative to prepare a report for the Governor, President of the Senate, and Speaker of the House of Representatives by December 1 each year, starting in 2025, that identifies and evaluates performance and the effects of grants issued through the Cancer Innovation Fund on cancer treatment, research, screening, diagnosis, prevention, practitioner and workforce education, and survivorship. The report must include the following:
 - Amounts of grant funds awarded to each awardee.
 - Descriptions of each awardee's research or project that includes, but need not be limited to: goals or projected outcomes, population to be served, and research methods or project implementation plan.
 - An assessment of awardees of grant funds that evaluates performance toward achieving objectives specified in their grant funds applications.
 - Recommendations for best practices that may be implemented by health care providers in this state that diagnose, treat, and screen for cancer, based on the outcomes of projects funded through the Cancer Innovation Fund.

Annual Report to the CCRAB

The bill requires the report that the DOH, in conjunction with participating NCI-designated cancer centers, must provide to the Florida Cancer Control and Research Advisory Council (CCRAB) by July 1 each year, to include a description of the numbers and types of cancer cases seen annually at each participating cancer center.

Cancer Connect Collaborative

The bill provides Legislative findings and creates the Cancer Connect Collaborative Research Incubator (Incubator) within the DOH, to be overseen by the Collaborative, to provide funding for a targeted area of cancer research for a five-year period. For the five-year period beginning July 1, 2025, the bill provides that the Incubator's targeted area of cancer research will be pediatric cancer.

Contingent on the appropriation of funds, grants issued through the Incubator will be awarded through a peer-reviewed, competitive process. Emphasis will be given to applicants that focus on improving both research and treatment through greater participation in clinical trials that pertain to the targeted area of cancer research, including:

- Identifying ways to increase enrollment in cancer clinical trials;
- Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
- Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
- Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

Preference for Incubator funding may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, to support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks.

The bill provides that applications for Incubator funding may be submitted by any Florida-based specialty hospital as defined in <u>s. 395.002(28)(a)</u>, F.S., that provides cancer treatment for patients from birth to 18 years old. All qualified applicants are to have equal access and opportunity to compete for the research funding. Incubator grants will be recommended by the Collaborative and awarded by the DOH on the basis of scientific merit, as determined by a competitively open and peer-reviewed process to ensure objectivity, consistency, and high quality.

To ensure that all proposals for research funding through the Incubator are appropriate and are evaluated fairly on the basis of scientific merit, the DOH is directed by the bill to appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish its priority score. The priority scores will be forwarded to the Collaborative and must be considered in determining which proposals the Collaborative recommends for funding.

The Collaborative and the panels are directed by the bill to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest regarding the assessment of Incubator grant applications. A member of the Collaborative or a panel may not participate in any discussion or decision of the Collaborative or a panel with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.

Each recipient of Incubator grant funds must enter into an allocation agreement with the DOH, and each allocation agreement must include all of the following:

- A line-item budget narrative documenting the annual allocation of funds to a recipient.
- A cap on the annual award of 15 percent for administrative expenses.
- A requirement for the recipient to submit quarterly reports of all expenditures made by the recipient with funds received through the Incubator.

- A provision to allow the department and other state auditing bodies to audit all financial records, supporting documents, statistical records, and any other documents pertinent to the allocation agreement.
- A provision requiring the annual reporting of outcome data and protocols used in achieving those outcomes.

The bill requires that, beginning December 1, 2026, and annually through December 1, 2030, the Collaborative must submit a report to the Governor, President of the Senate, and Speaker of the House of Representatives that evaluates research conducted through the Incubator and provides details on outcomes and findings available through the end of the fiscal year immediately preceding each report.

The bill provides that if the Collaborative decides to recommend that the Incubator be extended beyond its five-year lifespan, the Collaborative is directed to make such recommendation in the report due December 1, 2029, and to include a recommendation for the next targeted area of cancer research. The report due on December 1, 2030, must include:

- Details of all results of the research conducted with Incubator funding that has been completed or the status of research in progress; and
- An evaluation of all research conducted with Incubator funding during the five fiscal years preceding the report. (Section <u>2</u>).

Bascom Palmer Eye Institute VisionGen Initiative

• The bill creates a new cancer research initiative within the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley program). The bill establishes the Bascom Palmer Eye Institute VisionGen Initiative and provides that the purpose of the initiative is to advance genetic and epigenetic research on inherited eye diseases and ocular oncology by awarding grants through the peer-reviewed, competitive process statutorily-required under the Bankhead-Coley program. The initiative is subject to the annual appropriation of funds by the Legislature. (Section <u>3</u>).

Medical Marijuana Registry

• The bill requires the Department of Health (DOH) to revoke medical marijuana registration if a patient or caregiver is convicted or pleads guilty or no contest to, regardless of adjudication, a violation ch. 893, F.S., if such violation was for trafficking in, the sale, manufacture, or delivery of, or possession with intent to sell, manufacture, or deliver a controlled substance. If such person wishes to seek reinstatement of his or her registration as a qualified patient, the person may submit a new application accompanied by a notarized attestation by the applicant that he or she has completed all terms of incarceration, probation, community control, or supervision related to the offense. A person who knowingly makes a false attestation under this paragraph commits a misdemeanor of the second degree. (Section <u>4</u>).

Nursing Homes

Consumer Satisfaction Survey

The bill requires the Agency for Health Care Administration (AHCA) to develop user-friendly consumer satisfaction surveys to capture resident and family member satisfaction with care provided by nursing home facilities. The surveys must be based on a core set of consumer satisfaction questions to allow for consistent measurement and must be administered annually to a random sample of long-stay and short-stay residents of each facility and their family members. The survey tool must be based on an agency-validated survey instrument whose measures have received an endorsement by the National Quality Forum. The AHCA is required under the bill to:

- Specify the protocols for conducting the consumer satisfaction surveys, ensuring survey validity, reporting survey results, and protecting the identity of individual respondents;
- Make aggregated survey data available to consumers on the AHCA's website in a manner that allows for comparison between nursing home facilities; and
- Allow family members, guardians, or other resident designees to assist a resident in completing the survey and also prohibit employees and volunteers of the nursing home, or of a corporation or business entity

with and ownership interest in the nursing home, from attempting to influence a resident's responses to the survey. (Section 5).

The bill also requires each nursing home to conduct, at least biennially, a patient safety culture survey using the applicable survey on patient culture developed by the federal Agency for Health Care Research and Quality. The bill requires each facility to conduct the survey anonymously and allows facilities to contract with a third party to administer the survey. The survey data, including participation rates, must be submitted to the AHCA biennially and each facility must develop an internal action plan between surveys to improve survey results and submit the plan to the AHCA. (Section $\underline{6}$). AHCA is required to include the results of the consumer satisfaction surveys in its Nursing Home Guide. (Section $\underline{7}$).

Certified Medical Director

The bill also requires the medical director of each nursing home facility to obtain designation as a certified medical director by the American Medical Directors Association, hold a similar credential bestowed by an organization recognized by the AHCA, or be in the process of seeking such designation or credentialing, according to parameters adopted by agency rule, by January 1, 2026. The bill also requires the AHCA to include the name of each nursing home's medical director on the facility's provider profile published on the AHCA's website. (Section <u>7</u>).

Health Information and Reporting Data

The bill requires each nursing home that maintains certified electronic health records technology to make available all admit, transfer, and discharge data to the Florida Health Information Exchange. The bill allows AHCA to adopt rules to implement this subsection. (Section 8). The bill specifies that, beginning January 1, 2026, AHCA is required to impose an administrative fine of \$10,000 per violation against a nursing home or the home office of a nursing home that fails to comply with the requirement to submit specified audited financial data to the Florida Nursing Home Uniform Reporting System (FNHURS). Additionally, the bill specifies that failing to file the report during any subsequent 10-day period occurring after the due date constitutes a separate violation until the report has been submitted. AHCA is required to adopt rules to implement the fine and requires the rules to include provisions for a home office to present factors in mitigation of the imposition of the fine's full dollar amount. AHCA may determine not to impose the fine's full dollar amount upon a demonstration that the full fine is inappropriate under the circumstances. (Section 9).

The bill also exempts state-owned nursing homes from the FNHURS reporting requirement under current law, and clarifies that a facility that is fined under <u>s. 408.061, F.S.</u>, for an FNHURS violation, as described above, may not also be fined for such violation under <u>s. 408.08, F.S.</u> (Section <u>10</u>)

Medicaid Quality Incentive Program

The bill also requires the AHCA to, by October 1, 2025, and each year thereafter, submit a report to the Governor and the Legislature on each Medicaid Quality Incentive Program (QIP) payment made. The report must, at a minimum, include:

- The name of each facility that received a QIP payment and the dollar amount of such payment each facility received.
- The total number of quality incentive metric points awarded by the AHCA to each facility and the number of points awarded by the agency for each individual quality metric measured.
- An examination of any trends in the improvement of the quality of care provided to nursing home residents which may be attributable to incentive payments received under the QIP. The AHCA is required to include an examination of trends both for the program as a whole as well as for each individual quality metric used by the AHCA to award program payments.

The bill also directs the AHCA to include the result of customer satisfaction surveys as a quality measure when sufficient data has been collected to be statistically and scientifically valid. (Section <u>13</u>)

The bill requires the AHCA to contract with a third-party vendor to complete a comprehensive study of nursing home quality incentive programs in other states. The study must include a detailed analysis of quality incentive programs, identify components of programs that have improved quality outcomes, and make recommendations to modify or enhance Florida's existing Medicaid Quality Incentive Program. The study must also include a review of

technologies applicable to nursing home care and payment structures related to ventilator care, bariatric services, and behavioral health services. The final report must be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 5, 2026. (Section <u>20</u>).

Medicaid Enrollment for Permanently Disabled Individuals

The bill requires the Agency for Health Care Administration (AHCA) to seek federal approval, by October 1, 2025, to provide lifelong eligibility for permanently disabled Medicaid-qualified individuals receiving Medicaid covered:

- Institutional care services;
- Hospice services; or
- Home and community-based services in the iBudget waiver for persons with developmental disabilities or in the Long-Term Care (LTC) managed care program.

To qualify for lifelong eligibility the bill requires a permanently disabled individual to:

- Have an income at or below 88 percent of the federal poverty level and assets below established limitations;
- Be ineligible for Medicare, or if eligible for Medicare, also be eligible for and receiving Medicaid-covered institutional care services, hospice services, or home and community-based services; and
- Have their qualifying disability certified as being permanent by a licensed physician.

The bill requires an individual who is permanently disabled and presumed eligible for Medicaid to notify AHCA and the Department of Children and Families (DCF) of any material change in their disability or economic status that may result in their ineligibility from Medicaid. The bill authorizes DCF to conduct a redetermination of the individual's eligibility status. The bill requires DCF to notify the individual prior to commencing a redetermination and to provide the results to the individual upon conclusion of a redetermination. The bill requires AHCA and DCF to develop a process to facilitate such notification. (Section <u>11</u>)

Blood-Based Biomarker Testing

The bill requires managed care plans to provide coverage for medically necessary blood-based biomarker tests for colorectal cancer screening at the same scope and frequency as the Medicaid program provides for other medically necessary tests or screenings for colorectal cancer. (Section <u>17</u>). The bill also allows AHCA to cover, as an optional Medicaid service, biomarker tests at an in-network or out-of-network laboratory facility for colorectal cancer screening covered under a National Coverage Determination from the Centers for Medicare and Medicaid Services. (Section <u>12</u>).

The Graduate Medical Education Committee

The bill abolishes the Graduate Medical Education Committee. (Section <u>14</u>).

Training, Education, and Clinicals in Health Funding Program

The bill expands the Training, Education, and Clinicals in Health (TEACH) Funding Program to include certain nonprofits and provides for reimbursement of nursing students. (Section <u>15</u>).

Achieved Savings Rebate (ASR)

The bill requires AHCA to notify the certified public accountant who completed the audit of the Medicaid managed care plan financials and Medicaid related transaction records, of any deficiencies in the audit report. The CPA is required to correct such deficiencies in the audit report and resubmit a revised report to the agency before the report is considered final. The audit report results are only considered dispositive, once the report is finalized. (Section <u>16</u>).

Medicaid Financial Assistance

The bill allows AHCA to exceed the Medicaid financial assistance cap, if the agency determines it is cost effective to do so, for high cost patients who have chosen to opt-out of Medicaid coverage and use their Medicaid premiums to help pay their share of an employer provided plan. (Section <u>18</u>).

Program for All Inclusive Care for the Elderly

The bill amends s.430.84, F.S., to allow a proposed PACE organization to submit to AHCA a letter of intent to provide PACE services in a defined geographic service area where an existing PACE organization is under contract and has been operating for at least 10 years. AHCA shall determine if there is justification for the proposed PACE organization. (Section <u>19</u>).

The bill has an effective date of July 1, 2025. (Section <u>21</u>).

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

Cancer Connect Collaborative Research Incubator (Incubator)

Creation of a new biomedical research grant program, the Cancer Connect Collaborative Research Incubator (Incubator), may have a significant negative fiscal impact on the Department of Health (DOH). The Incubator does not authorize an administrative allowance.

Two similar biomedical research grant programs were recently established that also do not include administrative allowances: the Cancer Innovation Fund (2023) and the Andrew John Anderson Pediatric Rare Disease Research Grant Program (2024). In Fiscal Year 2023-2024 the DOH received 147 Cancer Innovation Fund applications and granted 30 awards. For Fiscal Year 2024-2025, the DOH projects up to 90 awards. According to the DOH's Fiscal Year 2025-2026 Legislative Budget Request, current staff cannot absorb the workload associated with these grant programs.

The Fiscal Year 2025-2026 General Appropriations Act provides \$30,000,000 in recurring general revenue funds for the Incubator.

Bascom Palmer Eye Institute VisionGen Initiative

The bill creates a new cancer research effort by establishing the Bascom Palmer Eye Institute VisionGen Initiative. Funding is subject to an annual appropriation of funds by the Legislature.

Office of Medical Marijuana Use

The bill has no fiscal impact on state expenditures, however, it may have a negative impact on state revenues to the extent the bill decreases the number of qualified patients in the medical marijuana use registry.

Quality of Care in Nursing Homes

The bill conforms to SB 2500, the Fiscal Year 2025-2026 General Appropriations Act, which provides \$497,000 from the General Revenue Fund, of which \$356,500 is nonrecurring, for the Agency for Health Care Administration (AHCA) to implement and maintain the Nursing Home Patient Satisfaction Survey and the Nursing Home Patient Safety Culture Survey.

In addition, SB 2500 provides \$750,000 in nonrecurring general revenue funds and \$750,000 in nonrecurring funds from the Medical Care Trust Fund for the AHCA to contract with a third-party vendor to complete a comprehensive study of nursing home quality incentive programs in other states and submit a final report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 5, 2026.

The bill may have an indeterminate positive fiscal impact on state revenues to the extent a nursing home or the home office of a nursing home fails to comply with the requirement to submit specified audited financial data to the FNHURS and is subject to an administrative fine of \$10,000 per violation.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Dental Student Loan Repayment Program

Section <u>381.4019</u>, F.S., establishes the Dental Student Loan Repayment Program (DSLR Program) to support the state Medicaid program and promote access to dental care by supporting dentists and dental hygienists who treat medical underserved populations in dental health professional shortage areas or medically underserved areas. The program authorizes student loan repayment awards for up to \$50,000 for dentists, and \$7,500 for dental hygienists, but caps the loan at 20 percent of the principal loan amount at the time of application. A dentist or dental hygienist may receive up to a maximum of 5 awards, one award for each year he or she maintains eligibility for the program for the entire year.¹

DSLR loan awardees must maintain active employment in a public health program or private practice that serves Medicaid recipients and other low-income patients and is in a dental health professional shortage area or medically underserved area.²

Florida Cancer Research Programs

The Legislature funds cancer research in Florida through four main programs: William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program), the Casey DeSantis Cancer Research Program (Casey DeSantis Program), the Live Like Bella Initiative – Pediatric Cancer Research Program (Live Like Bella Initiative), and the Cancer Innovation Fund. Currently, \$200.5 million is appropriated annually for these research programs as follows:³

- Bankhead-Coley Program \$10 million Biomedical Trust Fund
- Casey DeSantis Cancer Research Program \$127.5 million (\$111.1 General Revenue; \$16.4 Biomedical Trust Fund)
- Live Like Bella Initiative \$3 million Biomedical Trust Fund
- Florida Cancer Innovation Fund \$60 million Biomedical Research Trust Fund

William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

In 2006, the Legislature created the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program to advance progress toward cures for cancer through grants awarded through a peer-reviewed, competitive process.⁴

The program provides grants for cancer research to further the search for cures for cancer, by pursuing the following goals:⁵

- Significantly expand cancer research capacity in Florida.
- Improve both research and treatment through greater pediatric and adult participation in clinical trials networks.
- Reduce the impact of cancer on disproportionately impacted individuals.

Currently, the Bankhead-Coley Program is funded at \$10 million annually.⁶

¹ Section <u>381.4019(3)</u>, F.S.

² Section <u>381.4019(2), F.S.</u>

³ Chapter 2024-231, Laws of Fla. See specific appropriations 456C, 457A, 457C, and 457B, respectively.

⁴ Section <u>381.922(1), F.S.</u>

⁵ Section <u>381.922(2), F.S.</u>

⁶ Chapter 2024-231, Laws of Fla. See specific appropriation 456C.

The Casey DeSantis Cancer Research Program

In 2014, the Legislature created the Florida Consortium of National Cancer Institute (NCI) Centers Program, which was renamed as the Casey DeSantis Cancer Research Program (Casey DeSantis Program) in 2022. The Casey DeSantis Program was established to:⁷

- Enhance the quality and competitiveness of cancer care in Florida;
- Further a statewide biomedical research strategy directly responsive to the health needs of Florida's citizens; and
- Capitalize on potential educational opportunities available to students.

The Florida Department of Health (DOH) is required to make payments to cancer centers recognized by the NCI as NCI-designated comprehensive cancer centers, cancer centers, and cancer centers working toward achieving NCI designation.⁸

The NCI designates institutions as:9

- Comprehensive Cancer Centers focused on substantial transdisciplinary research that bridges all cancerrelated research areas;
- Cancer Centers focused on one research area such as clinical, prevention, cancer control or population science research; or
- Basic Laboratory Cancer Centers focused on laboratory research and work collaboratively with other institutions.

A participating cancer center's annual allocation of funds is determined by a statutory tier-weighted formula that factors in a cancer center's reportable cancer cases; peer-review costs; and biomedical education and training.¹⁰ The tier designations are weighted based on the participating cancer center's NCI-designation status. The program's three-tier designations are:¹¹

- Tier 1: NCI-designated comprehensive cancer centers;
- Tier 2: NCI-designated cancer centers; and
- Tier 3: Cancer centers seeking NCI designation and meeting additional criteria related to their research and biomedical education.

Currently, there are two NCI-designed comprehensive cancer centers and two NCI-designated cancer centers in Florida:¹²

- H. Lee Moffitt Cancer Center Comprehensive Cancer Center
- Mayo Clinic Cancer Center Comprehensive Cancer Center
- The University of Florida (UF) Health Shands Cancer Hospital Cancer Center
- University of Miami (UM) Sylvester Cancer Center Cancer Center

Starting July 1, 2025, the DOH, in conjunction with participating cancer centers, must provide an annual report to the Cancer Control and Research Advisory Council (CCRAB) by July 1. The report must include the following:¹³

- An analysis of trending age-adjusted cancer mortality rates in the state by age group, geographic region, and type of cancer.
- Identification of trends in overall federal funding, broken down by institutional source, for cancer-related research in the state.
- A list and narrative description of collaborative grants and interinstitutional collaboration among participating cancer centers, a comparison of collaborative grants in proportion to the grant totals for each

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⁷ Section <u>381.915(2), F.S.</u>

⁸ Id.

⁹ National Cancer Institute, NCI-Designated Cancer Centers, *available at*:

https://www.cancer.gov/research/infrastructure/cancer-centers (last visited June 18, 2025).

¹⁰ Section <u>381.915(3), F.S.</u>

¹¹ Section <u>381.915(4), F.S.</u>

¹² National Cancer Institute, NCI-Designated Cancer Centers, "Find a Cancer Centers" directory, *available at*:

https://www.cancer.gov/research/infrastructure/cancer-centers/find (last visited June 18, 2025).

¹³ Section <u>381.915(10)</u>, F.S. Prior to 2025, the report was required once every three years.

cancer center, a catalog of retreats and progress seed grants using state funds, and targets for collaboration in the future and reports on progress regarding such targets where appropriate.

Live Like Bella Initiative - Pediatric Cancer Research

The Live Like Bella Pediatric Cancer Research Initiative was established to advance progress toward curing pediatric cancer through grants awarded through a peer-reviewed, competitive process.¹⁴ The Initiative will provide grants for research to further the search for cures for pediatric cancer, by pursuing the following goals to:¹⁵

- Significantly expand pediatric cancer research capacity in Florida.
- Improve both research and treatment through greater pediatric enrollment in clinical trial networks.
- Reduce the impact of pediatric cancer on disproportionately impacted individuals.

Currently, the Live Like Bella Initiative is funded with \$3 million annually.¹⁶

Florida Cancer Innovation Fund

The Florida Cancer Innovation Fund was established in Fiscal Year 2023-2024 to fund projects focused on innovative research in cancer care and treatment. The funding aims to provide opportunities to break down longstanding silos between researchers, cancer facilities, and medical providers to improve cancer research and treatment through innovative approaches to data infrastructure and best practices.¹⁷ Funding is limited to Florida-based institutions.

The projects funded through Cancer Innovation Fund grant awards are required to focus on at least one of three goal areas below:¹⁸

- Data to identify the reasons data is slow to move or hard to access and ways to dismantle those barriers.
- Best Practices to streamline, encourage, and incentivize the sharing of treatment best practices among public and private entities.
- Innovation to make advancements in cutting-edge technology and clinical treatments.

Currently, the Cancer Innovation Fund is appropriated \$60 million annually.¹⁹

Florida Cancer Control and Research Advisory Council (CCRAB)

The Florida Cancer Control and Research Advisory Council (CCRAB) was established by the Legislature as an advisory body appointed to function on a continuing basis for the study of cancer and to make recommendations on solutions and policy alternatives to the Board of Governors and the State Surgeon General.²⁰ The CCRAB closely monitors Florida's cancer burden and recommends changes in policies, systems, and environments that lead to improved prevention, early detection, high-quality treatment, and increased cancer survival rates.²¹

- The Council consists of 16 members:²²
- The State Surgeon General or his or her designee within the DOH;
- A representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;

¹⁶ Chapter 2024-231, Laws of Fla. See specific appropriations 457C.

¹⁷ Department of Health, Funding Opportunity Announcement, The Florida Cancer Innovation Fund, *available at* <u>https://www.floridahealth.gov/provider-and-partner-resources/research/florida-cancer-innovation-fund/index.html</u> (last visited June 18, 2025).

SUMMARY

¹⁴ Section <u>381.922(2), F.S.</u>

¹⁵ Department of Health, Biomedical Research Program Funding Announcement, Fiscal Year 2023-2024, *available at:* <u>https://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/BRACFOAApprovedFINAL.pdf</u> (last visited June 18, 2025).

¹⁸ Id.

¹⁹ Chapter 2024-231, Laws of Fla. See specific appropriation 457B.

²⁰ Section <u>1004.435, F.S.</u>

²¹ Florida Cancer Control and Research Advisory Council, CCRAB Annual Report 2024, The State of Cancer in Florida, *available at*: <u>https://www.ccrab.org/_cache/files/c/3/c388cd5a-94e1-4342-b946-</u>

<u>d21f872724cc/72B5F6981BBF2571E5C3B73AF0DC1169.2024ccrab-annualreport-final.pdf</u> (last visited June 18, 2025). ²² Section <u>1004.435(4), F.S.</u>

- A representative of the Sylvester Comprehensive Cancer Center of the University of Miami;
- A representative of the University of Florida Shands Cancer Center;
- A representative of the Mayo Clinic in Jacksonville;
- A representative of the American Cancer Society;
- A representative of the Association of Community Cancer Centers;
- A member of the Florida Hospital Association who specializes in the field of oncology;
- A member of the Florida Medical Association who specializes in the field of oncology;
- A representative of the Florida Nurses Association who specializes in the field of oncology;
- A representative of the Florida Osteopathic Medical Association who specializes in the field of oncology;
- A specialist in pediatric oncology research or clinical care appointed by the Governor;
- A specialist in oncology clinical care or research appointed by the President of the Senate;
- A current or former cancer patient or a current or former caregiver to a cancer patient appointed by the Speaker of the House of Representatives;
- A member of the House of Representatives appointed by the Speaker of the House of Representatives; and
- A member of the Senate appointed by the President of the Senate.

CCRAB members serve four-year terms.²³

Florida Cancer Connect Collaborative

Established in 2023, the Florida Cancer Connect Collaborative²⁴ (Collaborative) is an initiative begun by First Lady Casey DeSantis in partnership with the DOH and the Agency for Health Care Administration (AHCA). It was created by executive action of the Governor. The Collaborative originated as a team composed of medical professionals and government officials to analyze Florida's approach to combatting cancer. The original goal of the Collaborative was to break down long-standing silos between researchers, cancer facilities, and medical providers to improve cancer research and treatment. When first created, according to the Governor and First Lady, the Collaborative had five main objectives:²⁵

- Data The Collaborative will seek to identify the reasons data is slow to move or hard to access and dismantle those barriers.
- Best practices The Collaborative will seek to streamline, encourage and incentivize the sharing of treatment best practices among public and private entities so that everyone is treated with the most effective treatment possible.
- Innovation The Collaborative will identify the reasons that technology gets held up whether it be special interests, over-litigiousness or bureaucratic red tape and recommend ways to eliminate these barriers.
- Funding The Collaborative will provide recommendations for the implementation of the Governor's proposed \$170 million in funding to improve the pace of cancer research and novel technologies.
- Honesty The Collaborative will be tasked with identifying the ways to ensure cancer causes, treatment, prevention, and diagnosis information is available and easy to access.

In 2024, the Legislature codified the Collaborative in Florida law, revising the mission of the Casey DeSantis Program to include a goal of promoting "the provision of high-quality, innovative health care for persons undergoing cancer treatment in this state" and to "make cancer innovation grant funding available through the Cancer Innovation Fund to health care providers and facilities that demonstrate excellence in patient-centered cancer treatment or research."²⁶

²⁵ Florida Governor Ron DeSantis, First Lady Casey DeSantis Announces the Cancer Connect Collaborative to Explore Innovative Strategies for Cancer Treatment and Care, *available at*: <u>https://www.flgov.com/2023/02/23/first-lady-casey-DeSantis-announces-the-cancer-connect-collaborative-to-explore-innovative-strategies-for-cancer-treatment-and-care/</u> (last visited June 18, 2025).

²⁶ See ch. 2024-247, Laws of Florida.

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²³ Section <u>1004.435(4)</u>, F.S.

²⁴ The Cancer Connect Collaborative is an expansion of Cancer Connect, an initiative launched by First Lady Casey DeSantis in August 2022 to provide cancer information and survivor stories.

The Collaborative is now a council²⁷ as defined in <u>s. 20.03, F.S.</u>, created within the DOH to advise the department and the Legislature on developing a holistic approach to the state's efforts to fund cancer research, cancer facilities, and treatments for cancer patients. The Collaborative is authorized to make recommendations on proposed legislation, proposed rules, best practices, data collection and reporting, issuance of grant funds, and other proposals for state policy relating to cancer research or treatment.

The Collaborative is chaired by the State Surgeon General who serves as an ex officio, non-voting member. The remaining membership of the Collaborative is composed as follows, all of whom are voting members:

- Two members appointed by the Governor, one member appointed by the President of the Senate, and one member appointed by the Speaker of the House of Representatives, prioritizing their appointments on members who have the following experience or expertise:
- The practice of a health care profession specializing in oncology clinical care or research;
- The development of preventive and therapeutic treatments to control cancer;
- The development of innovative research into the causes of cancer, the development of effective treatments for persons with cancer, or cures for cancer; or
- Management-level experience with a cancer center licensed under ch. 395, F.S.
- A Florida resident who can represent the interests of cancer patients in this state, appointed by the Governor.

Members of the Collaborative have staggered terms, and vacancies are to be filled in the same manner as first appointed. Members serve without compensation but are entitled to reimbursement for per diem and travel expenses pursuant to <u>s. 112.061, F.S.</u>

The Collaborative meets as necessary, but at least quarterly, at the call of the chair. A majority of the members of the Collaborative constitute a quorum, and a meeting may not be held with less than a quorum present. To establish a quorum, the Collaborative may conduct its meetings through teleconference or other electronic means. The DOH is required to provide reasonable and necessary support staff and materials to assist the Collaborative in the performance of its duties.

The Collaborative was required in 2024 to develop a long-range comprehensive plan for the Casey DeSantis Program and solicit input from cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers. The long-range plan was required to be submitted to the President of the Senate, the Speaker of the House of Representatives, and the Executive Office of the Governor no later than December 1, 2024,²⁸ to include, but not be limited to, the following components:

- Expansion of grant funding opportunities to include a broader pool of Florida-based cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers to receive funding through the Cancer Innovation Fund.
- An evaluation to determine metrics that focus on patient outcomes, quality of care, and efficacy of treatment.
- A compilation of best practices relating to cancer research or treatment.

The Collaborative must advise the DOH on the awarding of grants issued through the Cancer Innovation Fund. During any fiscal year for which funds are appropriated, the Collaborative must recommend to the DOH the awarding of grants to support innovative cancer research and treatment models, including emerging research and treatment trends and promising treatments that may serve as catalysts for further research and treatments. The Collaborative is directed to give priority to applications seeking to expand the reach of innovative cancer treatment models into underserved areas of the state. The Collaborative must review all grant applications and make grant funding recommendations to the DOH, and the DOH is directed under the bill to make final grant allocation awards.

²⁸ The long-range plan was completed and submitted as required by statute. It is *available at*:

²⁷ Section <u>20.03, F.S.</u>, defines a "council" or an "advisory council" as an advisory body created by specific statutory enactment and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.

https://www.floridahealth.gov/provider-and-partner-resources/research/index1.html (last visited June 18, 2025).

Medical Marijuana

Florida Comprehensive Drug Abuse Prevention and Control Act, Ch. 893, F.S.

Chapter 893, F.S., known as the "Florida Comprehensive Drug Abuse Prevention and Control Act (Act)," is intended to comprehensively address drug abuse prevention and control in Florida. The Act generally provides laws relating to the scheduling of controlled substances, the penalties for the use, possession, sale and trafficking of such substances, and exceptions from such penalties such as for prescriptions from a pharmacist or healthcare practitioner.²⁹

Department of Health's Office of Medical Marijuana Use

The Office of Medical Marijuana Use is charged with writing and implementing DOH's rules for medical marijuana, overseeing the statewide Medical Marijuana Use Registry, licensing Florida businesses to cultivate, process, and dispense medical marijuana to qualified patients, and certifying marijuana testing laboratories to ensure the health and safety of the public as it relates to marijuana.

Departmental Authority to Revoke the Registration of Qualified Patient or Caregiver

Currently, the DOH may suspend or revoke the registration of a qualified patient or caregiver if the qualified patient or caregiver:³⁰

- Provides misleading, incorrect, false, or fraudulent information to the department;
- Obtains a supply of marijuana in an amount greater than the amount authorized by the physician certification;
- Falsifies, alters, or otherwise modifies an identification card;
- Fails to timely notify the DOH of any changes to his or her qualified patient status; or
- Violates the requirements of <u>s. 381.986, F.S.</u>, or any rule adopted by the DOH pursuant to <u>s. 381.986, F.S.</u>

Current law also requires the DOH to immediately suspend the registration of a qualified patient or caregiver charged with a violation of chapter 893 until final disposition of any alleged offense. Thereafter, the DOH *may* extend the suspension, revoke the registration, or reinstate the registration of a qualified patient.³¹

The DOH may revoke the registration of a qualified patient or caregiver who cultivates marijuana or who acquires, possesses, or delivers marijuana from any person or entity other than a medical marijuana treatment center.³² The department must revoke the registration of a qualified patient, and the patient's associated caregiver, upon notification that the patient no longer meets the criteria of a qualified patient.³³

Nursing Homes

Nursing homes in Florida are licensed under Part II of ch. 400, F.S., and provide 24-hour-a-day nursing care, case management, health monitoring, personal care, nutritional meals and special diets, physical, occupational, and speech therapy, social activities and respite care for those who are ill or physically infirm.³⁴ Currently, there are 696 nursing homes licensed in Florida.³⁵ Of the 696 licensed nursing homes, 668 are certified to accept Medicare or Medicaid and consequently must follow federal Centers for Medicare & Medicaid Services (CMS) requirements for nursing homes.³⁶

²⁹ See chapter 893, F.S.

³⁰ Section <u>381.986(5)(c), F.S.</u>

³¹ Section 381.986(5)(d) and (e), F.S.

³² Section 381.986(5)(f). F.S.

³³ Section <u>381.986(5)(g), F.S.</u>

³⁴ Agency for Health Care Administration webpage, nursing homes, available at

https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Long_Term_Care/Nursing_Homes.shtml (last visited June 18, 2025).

³⁵ Florida Health Finder Report, available at <u>https://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx</u> (last visited June 18, 2025).

³⁶ Id. Search for nursing homes that accept Medicaid or Medicare as payment.

Nursing Home Medical Directors

Florida administrative code requires that each nursing home have only one physician, who is licensed under ch. 458 or ch. 459, F.S., that is designated as its medical director.³⁷ If the medical director does not have hospital privileges, he or she is required to be certified or credentialed through a recognized certifying or credentialing body, such as The Joint Commission, the American Medical Directors Association, the Healthcare Facilities Accreditation Program of the American Osteopathic Association, the Bureau of Osteopathic Specialists of the American Osteopathic Association, the Florida Medical Directors Association or a health maintenance organization licensed in Florida.³⁸ One physician may be the medical director of up to 10 nursing homes at any one time and must have his or her principal office within 60 miles of all facilities for which he or she serves as medical director.³⁹

The medical director is required to visit each facility at least once a month, meet quarterly with the risk management and quality assurance committee of each facility, and must review for each facility:

- All new policies and procedures;
- All new incident and accident reports to identify clinic risk and safety hazards;
- The most recent grievance logs for any complaints or concerns related to clinical issues.⁴⁰

Additionally, the medical director must participate in the development of the comprehensive care plan for any resident for whom he or she is the attending physician.⁴¹

Nursing Home Financial Reports

Nursing homes are required to submit financial data to the AHCA pursuant to s. 408.061 (5)-(6), F.S. These provisions were added in 2021 by SB 2518 (ch. 2021-41, L.O.F.) and mirror provisions in current law that require other health care facilities to submit such data.⁴² Prior to July 1, 2021, nursing homes were exempt from this reporting requirement.

A nursing home must report, within 120 days after the end of its fiscal year, its actual financial experience for that fiscal year, including expenditures, revenues, and statistical measures. Such data may be based on internal financial reports that are certified to be complete and accurate by the chief financial officer of the nursing home. This actual experience must be audited and must include the fiscal year-end balance sheet, income statement, statement of cash flow, and statement of retained earnings and must be submitted to the AHCA in addition to the information filed in the Florida Nursing Home Uniform Reporting System (FNHURS).

The final rule for implementation of the FNHURS became effective November 1, 2023, and required nursing homes to begin submitting data to the FNHURS 30 days after that date in accordance with the end of each nursing home's fiscal year.⁴³ As of March 17, 2025, at least 536 of the 696 nursing homes had submitted to the AHCA.⁴⁴

Medicaid Quality Incentive Program

The Medicaid Quality Incentive Program (QIP) was established to ensure continued quality of care in nursing home facilities.⁴⁵ Nursing homes providers submit quality data directly to the federal Centers for Medicare and

⁴⁵ ch. 2017-129, s. 8, Laws of Fla.

³⁷ Fla. Admin. Code R. 59A-4.1075 (2015).

³⁸ Id.

³⁹ Fla. Admin. Code R. 59A-4.1075 (2015). Note: if the facility is a rural nursing home, the AHCA may approve a request to waive the distance requirement.

⁴⁰ Fla. Admin. Code R. 59A-4.1075 (2015).

⁴¹ *Id.*

⁴² See <u>s. 408.061(4), F.S.</u>

⁴³ Fla. Admin. Code R. 59E-4.102 (2023).

⁴⁴ Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, to Cynthia Barr, Chief Legislative Analyst, Senate Appropriations Committee on Health and Human Services (Mar. 18, 2025) (on file with the Senate Appropriations Committee on Health and Human Services). ⁴⁵ ab. 2017, 120, a. 9, Lawa of Ela

Medicaid Services, and the AHCA uses this information to rank all providers by 16 quality measures.⁴⁶ The quality metrics used include⁴⁷:

- **Process Measures**, which include flu vaccine, antipsychotic medication, and restraint quality metrics.
 - Providers whose fourth quarter measure score is at or above the 90th percentile for a particular measure will be awarded 3 points, those scoring from the 75th up to 90th percentiles will be awarded 2 points, and those scoring from the 50th up to 75th percentiles will receive 1 point.
 - Providers who score below the 50th percentile and achieve a 20 percent improvement from the previous year will receive 0.5 points.
- **Outcome Measures**, which include urinary tract infections, pressure ulcers, falls, incontinence, and decline in activities of daily living quality metrics.
 - Outcome Measures are scored and percentiles are calculated using the same methodology as Process Measures.
- **Structure Measures**, which include direct care staffing from the Medicaid cost report received by the rate setting cutoff date and social work and activity staff.
 - Structure Measures are scored and percentiles are calculated using the same methodology as Process Measures and Outcome Measures.
- **Credentialing Measures** which include CMS Overall 5-Star, Florida Gold Seal, Joint Commission Accreditation, and American Health Care Association National Quality Award.
 - Facilities assigned a rating of 3, 4, or 5 stars in the CMS 5- Star program will receive 1, 3, or 5 points, respectively.
 - Facilities that have either a Florida Gold Seal, Joint Commission Accreditation, or the silver or gold American Health Care Association National Quality Award on May 31 of the current year will be awarded 5 points.

By statute, nursing homes must meet the minimum threshold of the 20 percentile of included facilities to receive a quality incentive add-on payment, which is set at 10 percent of the 2016 non-property related payments of included facilities.⁴⁸ In the 2023-2024 federal fiscal year, the incentive pool totaled \$316 million with 534 of the 655 active providers receiving a quality incentive add-on to their rate.⁴⁹

Patient Safety Culture Surveys

Patient safety culture refers to the values, beliefs, and norms that are shared by health care practitioners and other staff throughout the organization that influence their actions and behaviors to support and promote patient safety. Patient safety culture can be measured by determining the values, beliefs, norms, and behaviors related to patient safety that are rewarded, supported, expected, and accepted in an organization. Culture exists at multiple levels, from the unit level to the department, organization, and system levels.⁵⁰

The federal Agency for Health Care Research and Quality (AHRQ) has developed a "Survey on Patient Safety Culture" (SOPS) program which develops and supports surveys of providers and staff that assess the extent to which their organizational culture supports patient safety and safe practices. All the SOPS surveys include a standard set of core items with comparable survey content across facilities and have been developed for the following settings of care:

- Hospitals.
- Medical Offices.
- Nursing Homes.
- Community Pharmacies.

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⁴⁶ Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, to Cynthia Barr, Chief Legislative Analyst, Senate Appropriations Committee on Health and Human Services (Feb. 25, 2025) (on file with the Senate Appropriations Committee on Health and Human Services).

⁴⁷ Fla. Admin. Code R. 59G-6.010(2)(y)(2021).

⁴⁸ Sections 409.908(2)(b)1.e. and f.

⁴⁹ Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, to Cynthia Barr, Chief Legislative Analyst, Senate Appropriations Committee on Health and Human Services (Feb. 25, 2025) (on file with the Senate Appropriations Committee on Health and Human Services).

⁵⁰ What is Patient Safety Culture?, ARHQ, June 2024, available at <u>https://www.ahrq.gov/sops/about/patient-safety-culture.html</u>, (last visited June 18, 2025).

• Ambulatory Surgery Centers.

The SOPS Program also offers optional supplemental item sets that can be added to the core surveys to assess additional content areas focusing on health information technology, patient safety, workplace safety, value and efficiency, and diagnostic safety.

SOPS surveys and supplemental item sets undergo a rigorous development and testing process. Because the surveys ask questions that have been developed and pilot tested using a consistent methodology across a large sample of respondents, they are standardized and validated measures of patient safety culture.⁵¹ The areas that are assessed by the SOPS include:

- Communication About Error.
- Communication Openness.
- Organizational Learning—Continuous Improvement.
- Overall Rating on Patient Safety.
- Response to Error.
- Staffing.
- Supervisor and Management Support for Patient Safety.
- Teamwork.
- Work Pressure and Pace.⁵²

Florida law requires hospitals and ambulatory surgical centers (ASC) to conduct, at least biennially, a patient safety culture survey using the SOPS.⁵³ In order to implement the requirement, the AHCA has customized the AHRQ's patient safety survey instruments, and developed a database application to facilitate the required submission of patient safety culture survey data from Florida hospitals and ASCs to the agency as statutorily mandated.⁵⁴

Florida's Health Information Exchange Program

Founded in 2011, the Florida Health Information Exchange (FHIE) facilitates the secure statewide exchange of health information between health care providers, hospital systems, and payers. The AHCA governs the FHIE by establishing policy, convening stakeholders, providing oversight, engaging federal partners, and promoting the benefits of health information technology.

The FHIE electronically makes patient health information available to doctors, nurses, hospitals, and health care organizations when needed for patient care. The exchange of patient information is protected through strict medical privacy and confidential procedures. The FHIE is designed to improve the speed, quality, safety, and cost of patient care.

As part of the FHIE Services, Florida has developed an Encounter Notification Service (ENS) that delivers realtime notifications based off of Admit, Discharge, and Transfer (ADT) data from participating health care facilities. This data is provided to authorize health care entities to improve patient care coordination.⁵⁵

Training, Education, and Clinicals in Health Funding Program

Section <u>409.91256, F.S.</u>, establishes the Training, Education, and Clinicals in Health (TEACH) Funding Program provide a high-quality educational experience while supporting participating federally qualified health centers, community mental health centers, rural health clinics, and certified community behavioral health clinics by

⁵¹ Id.

⁵² What is Patient Safety Culture?, ARHQ, June 2024, available at <u>https://www.ahrq.gov/sops/about/patient-safety-culture.html</u>, (last visited June 18, 2025).

⁵³ Section <u>395.1012(4)</u>, F.S.

⁵⁴ Patient Safety Survey System User Guide, 2024, available at

https://ahca.myflorida.com/content/download/25680/file/PSCS%20System%20Guide 2022%2824%29EP.pdf, (last visited June 18, 2025).

⁵⁵ Agency for Health Care Administration, *Senate Bill 7016 (2024) Analysis*. (on file with the Senate Committee on Health Policy).

offsetting administrative costs and loss of revenue associated with training residents and students to become licensed health care practitioners. The program is intended to support the state Medicaid program and underserved populations by expanding the available health care workforce.⁵⁶

Qualified facilities may be reimbursed to offset the administrative costs or lost revenue associated with training students and residents who are enrolled in an accredited educational or residency program in Florida. Subject to appropriation, the AHCA may reimburse a qualified facility based on the number of clinical training hours reported at the following rates:

- A medical or dental resident at a rate of \$50 per hour.
- A first-year medical student at a rate of \$27 per hour.
- A second-year medical student at a rate of \$27 per hour.
- A third-year medical student at a rate of \$29 per hour.
- A fourth-year medical student at a rate of \$29 per hour.
- A dental student at a rate of \$22 per hour.
- An APRN student at a rate of \$22 per hour.
- A PA student at a rate of \$22 per hour.
- A dental hygiene student at a rate of \$15 per hour.
- A behavioral health student at a rate of \$15 per hour.⁵⁷

A qualified facility may not be reimbursed more than \$75,000 per fiscal year or \$100,000 if the facility operates a residency program.⁵⁸

Biomarker Testing

As of 2024, current law <u>s. 409.906(29), F.S.</u>, requires Medicaid to cover biomarker testing services for diagnosis, treatment, appropriate management, and ongoing monitoring of a recipient's disease or condition, provided the available medical and scientific evidence indicates that the specific biomarker test provides clinical utility to the recipient.

Colorectal Cancer

In 2025, the American Cancer Society (ACS) estimates that there will be 171,960 new cancer cases and 49,040 deaths from cancer in Florida alone. From these totals, ACS projects 12,330 new colorectal cancer cases in Florida and believes 3,970 Floridians may die from colorectal cancer complications.⁵⁹

The colon and the rectum, two parts of the large intestine, are common places for cancer to occur. Colorectal cancer is an uncontrolled growth of abnormal cells in the colon and, or rectum. Colorectal tumors often begin as small growths (polyps) on the inside of the large intestine. Polyps that are not removed eventually can become cancerous.⁶⁰

Risk Factors

The major and potential risk factors for colorectal cancer include:61

Major Risk Factors	Potential Risk Factors
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56 409.91256(1)

2024," CA: A Cancer Journal for Clinicians, Vol. 75, Issue 1, (Jan. 16, 2025)

⁵⁷ 409.91256(5)(a)

⁵⁸ 409.91256(5)(b)

⁵⁹ American Cancer Society, Cancer Facts & Figures: 2025, <u>https://www.cancer.org/content/dam/cancer-</u>

org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf (last visited June 18, 2025); See Rebecca Siegel, Tyler Kratzer, Angela Giaquinto, Hyuna Sung, and Ahmedin Jemal, "Cancer Statistics,

https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21871 (last visited June 18, 2025).

⁶⁰ Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023)

https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited June 18, 2025).

⁶¹ Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023)

https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited June 18, 2025).

•	Personal history of colorectal cancer.	٠	Cigarette smoking.
•	Personal history of colon polyps.	•	Sedentary lifestyle.
•	Certain inherited genes linked to colon	•	Low intake of fruits and vegetables.
	polyps and cancer.	•	High consumption of processed meats.
•	Inflammatory bowel disease, including	•	Low vitamin D levels.
	persistent ulcerative colitis and Crohn's.		
•	Family history of colorectal cancer.		

Symptoms

Polyps and early colorectal cancer generally don't cause symptoms. As a result, they are usually caught during screening. More advanced cancer can cause:⁶²

- More or less frequent bowel movements than usual.
- Diarrhea or constipation.
- Blood in the stool (bright red, black, or very dark).
- Narrowed stools (about the thickness of a pencil).
- Bloating, fullness, or stomach cramps.
- Frequent gas pains.
- A feeling that the bowel does not empty completely.
- Weight loss without dieting.
- Continuing fatigue.

Preventive Screening

Medical professionals believe the best defense against colorectal cancer is regular screening. Screening tests are designed to find polyps, which are abnormal, noncancerous growths that protrude from mucous membranes in the sinuses and colon lining, so they can be removed before they become cancerous.⁶³

The United States Preventative Services Task Force (Task Force), an independent, volunteer panel of experts in prevention, primary care, and evidence-based medicine, recommends that asymptomatic adults at average risk⁶⁴ for colorectal cancer being screening at age 45 because of a rising number of younger people diagnosed with the disease.⁶⁵ The U.S. Congress created the Task Force through the Patient Protection and Affordable Care Act in 2010 to review scientific evidence relating to the efficacy, appropriateness, and cost-effectiveness of clinical preventative services, and to make periodic recommendations for preventive-care services that most private insurers must cover without imposing cost sharing requirements.⁶⁶ However, the Supreme Court of the United States is considering the constitutionality of the Task Force this term.⁶⁷

⁶² Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) <u>https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z</u> (last visited June 18, 2025).

⁶³ Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) <u>https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z</u> (last visited June 18, 2025); Harvard Health Publishing, Medical Dictionary of Health Terms, Harvard Medical School, <u>https://www.health.harvard.edu/j-through-p#P-terms</u> (last visited June 18, 2025).

⁶⁴ The Task Force equates average risk with no prior diagnosis of colorectal cancer, adenomatous polyps, or inflammatory bowel disease; no personal diagnosis or family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer. United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁶⁵ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁶⁶ 42 U.S.C. §§ 299b-4, 300gg-13.

⁶⁷ The Court will issue this opinion during the first half of 2025. The debate turns on whether Task Force members are principal officers, which must be appointed by the President and confirmed by the Senate, or inferior officers, which are under the direct supervision of a duly confirmed presidential appointee. Task Force members have attributes of both principal and

In 2021, the Task Force concluded with high certainty that screening for colorectal cancer in adults aged 50 to 75 years has substantial net benefit, and concludes with moderate certainty that screening for colorectal cancer in adults 45 to 49 years has moderate net benefit. The assessment of net benefits applies only to stool-based tests with high sensitivity, colonoscopy, computed tomography (CT) colonography, and flexible sigmoidoscopy.⁶⁸ The 2021 Task Force recommendations did not include serum tests, urine tests, or capsule endoscopy for colorectal screening because of the limited available evidence. The Task Force identified a need for research on the accuracy and efficacy of emerging screening technologies such as serum-and-urine-based colorectal cancer screening tests and capsule endoscopy tests to potentially improve acceptance and adherence to colorectal cancer screening.⁶⁹

Notwithstanding the Supreme Court's impending decision, federal law currently requires the Task Force to review interventions and update recommendations relating to colorectal cancer screening in 2026.⁷⁰

Rates of colorectal cancer screening are among the highest of the cancers for which screening is recommended. Even so, according to recent data, 30% of eligible adults are not up to date with any type of recommended colorectal cancer screening, and the disease remains the second leading cause of cancer deaths in the United States.⁷¹ Medical professionals recommend various screening methods to detect colorectal cancer. In addition to the digital rectal examination, sigmoidoscopy, colonoscopy, and virtual colonoscopy screening tests, manufacturers produce less invasive and more convenient screenings tests. The table below indicates the Task Force recommendations for each type of colorectal cancer screening test.⁷²

Screening Test	Description	Recommended Screening Intervals
Blood-Based Biomarker Tests ⁷³	Blood-based biomarker tests, also known as liquid biopsy tests, use a blood sample, from blood collected from a vein in an arm, to identify signs of cancer-specific markers in the body, such as cancer cell waste or antibodies in response to cancer in the bloodstream.	No Recommendation

inferior officers, according to the U.S. Court of Appeals for the Fifth Circuit. Since the Task Force recommends colorectal cancer screening as preventive-service that private insurers must cover, the market for colorectal cancer screening tests may face a period of adjustment if the Supreme Court agrees with the U.S. Court of Appeals for the Fifth Circuit and invalidates the Task Force. *See Braidwood Management Inc. v. Becerra*, 104 F.4th 930 (5th Cir. 2024); *see* SCOTUSblog, *Kennedy v. Braidwood Management, Inc.*, (current through Mar. 22, 2025) <u>https://www.scotusblog.com/case-files/cases/becerra-v-braidwood-management-inc/</u> (last visited June 18, 2025).

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⁶⁸ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, 1966 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁶⁹ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966, 1976 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁷⁰ See 42 U.S.C. § 299b-4(2)(B).

⁷¹ Alyssa Voss, "Colorectal Cancer Screening: Where Does the Shield Liquid Biopsy Fit In?", National Cancer Institute, (Oct. 11, 2024) <u>https://www.cancer.gov/news-events/cancer-currents-blog/2024/shield-blood-test-colorectal-cancer-screening</u> (last visited June 18, 2025).

⁷² United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1969 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁷³ Jill Seladi Schulman, "How is Blood-Based Biomarker Testing Used for Colorectal Cancer?", Healthline, (Jul. 25, 2022) <u>https://www.healthline.com/health/colorectal-cancer/blood-based-biomarker-test-for-colorectal-cancer</u> (last visited June 18, 2025); Alyssa Voss, "Colorectal Cancer Screening: Where Does the Shield Liquid Biopsy Fit In?", National Cancer Institute, (Oct. 11, 2024) <u>https://www.cancer.gov/news-events/cancer-currents-blog/2024/shield-blood-test-colorectal-cancerscreening</u> (last visited June 18, 2025); Julie Utterback and Aaron Degagne, "A New Frontier in Cancer Screening and Treatment," Morningstar, (Feb. 11, 2021)

Fecal Immunochemical Tests (FIT) ⁷⁴	A fecal immunochemical test detects blood in the stool using antibiotics.	Every Year
Fecal Occult Blood Test (FOBT) ⁷⁵	A fecal occult blood test detects blood in the stool based on high-sensitivity chemical detection of blood.	Every Year
Stool DNA Tests ⁷⁶	A stool DNA test detects DNA biomarkers for cancer in cells shed from the lining of the colon and rectum into the stool.	Every 1-3 Years

In 2024, the worldwide market capitalization for colorectal cancer screening and diagnostic products was \$40 billion and may reach \$46.1 billion by 2029. North America holds a 60.8% market share.⁷⁷

The table below depicts a sample of colorectal cancer screening tests available in the U.S.

Screening Test	Products (FDA Approval Date)	Manufacturer
Blood-Based Biomarker Test	Epi proColon (2016) ⁷⁸	Epigenomics
	Shield (2024) ⁷⁹ Guardant 360 CDx (2020) ⁸⁰	Guardant Health
	PREEMPT CRC Study (Clinical Trials) ⁸¹	Freenome
FIT	InSure ONE (2017) ⁸²	Clinical Genomics
	OC-Light (2015) ⁸³	Eiken Chemical

⁷⁴ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021)

⁷⁷ Research and Markets, "Colorectal Cancer Screening Diagnostics Market Report 2025, with Profiles of Fujim, Olympus, Exact Sciences, Danaher, Guardant Health, Diacarta, Mainz Biomed, Novigenix, and more," Globe Newswire, (Mar. 20, 2025) <u>https://www.globenewswire.com/news-release/2025/03/20/3046315/0/en/Colorectal-Cancer-Screening-and-Diagnostics-Market-Report-2025-with-Profiles-of-Fujifilm-Olympus-Exact-Sciences-Danaher-Guardant-Health-Diacarta-Mainz-Biomed-Novigenix-and-more.html (last visited June 18, 2025).</u>

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁷⁵ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁷⁶ United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited June 18, 2025).

⁷⁸ United States Food and Drug Administration, Epi proColon – P130001 Approval Letter, United States Department of Health and Human Services (Apr. 12, 2016) <u>https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130001A.pdf</u> (last visited June 18, 2025)

 ⁷⁹ United States Food and Drug Administration, Shield – P230009 Approval Letter, United States Department of Health and Human Services (Jul. 26, 2025) <u>https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230009A.pdf</u> (last visited June 18, 2025).
 ⁸⁰ United States Food and Drug Administration, Guardant 360 CDx – P200010, United States Department of Health and Human Services (Aug. 7, 2020) <u>https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200010A.pdf</u> (last visited June 18, 2025).
 ⁸¹ Rachel Facci, "Blood Test Could Provide Colonoscopy Alternative for Colorectal Cancer Screening," American Society of Clinical Oncology, (Jan. 21, 2025) <u>https://www.asco.org/about-asco/press-center/news-releases/study-evaluates-new-bloodbased-test-colorectal-cancer</u> (Last visited June 18, 2025).

⁸² United States Food and Drug Administration, 510(k) Substantial Equivalence Determination Decision Summary: InSure ONE, (Oct. 5, 2017) <u>https://www.accessdata.fda.gov/cdrh_docs/reviews/K170548.pdf</u> (last visited June 18, 2025).

Press Release, "Clinical Genomics and Quest Diagnostics announce FDA 510(K) clearance of InSure ONE," (Nov. 13, 2017) https://newsroom.questdiagnostics.com/press-releases?item=137050 (last visited June 18, 2025).

⁸³ United States Food and Drug Administration, 510(k) Substantial Equivalence Determination Decision Summary: OC-Light, (Aug. 20, 2015) <u>https://www.accessdata.fda.gov/cdrh_docs/reviews/K143325.pdf</u> (last visited June 18, 2025).

ANALYSIS

Screening Test	Products (FDA Approval Date)	Manufacturer
FOBT	ColoSense (2024) ⁸⁴	Geneoscopy
	Instant-view-plus (2018) ⁸⁵	Alfa Scientific Designs
Stool DNA Tests	Cologuard Plus (2024) ⁸⁶	Exact Sciences Corp.
	Cologuard (2014) ⁸⁷	

Biomarker testing is a type of personalized or precision medicine where medical care is tailored to a person's specific genes, proteins, and other substances which may be present in a person's body.⁸⁸ Results of a biomarker test can help an individual find different options for treatment through the FDA-approved treatment regimens, off-label treatments, or clinical trials. Knowing that cancer or another disease does not have certain biomarkers can also save a patient from undergoing unnecessary treatment, treatment that has not been as successful in a particular diagnosis, or treatment which may not have a long-term result leading to the return of the cancer.⁸⁹

Medicaid

Evaluation and Management Services Coverage Policy

Medicaid covers medically necessary services rendered to a recipient by, or under the personal supervision of, a licensed medical or osteopathic physician for the treatment of an injury, illness, or disease, provided that the services rendered are within the physician's scope of practice. These services may be furnished in the physician's office, the Medicaid recipient's home, a hospital, a nursing facility, or elsewhere. However, Medicaid does not cover physician services that are clinically unproven, experimental, or for purely cosmetic purposes.⁹⁰

Florida Medicaid evaluation and management services provide for physician visits to maintain a recipient's health, prevent disease, and treat illness. The Medicaid Evaluation and Management Services Coverage Policy⁹¹ delineates the reimbursement policy for preventative services, including:

- One adult health screening every 365 days, for recipients age 21 years and older.
- Preventative medicine services for recipients under the age of 21 years.
- One evaluation and management visit per month, per recipient of custodial care facility services or nursing facility services.
- Unlimited office visits, as medically necessary, for recipients under the age of 21 years and pregnant recipients age 21 years and older.
- Two office visits per month, per specialty, for recipients age 21 years and older.

Laboratory Services Coverage Policy

https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230043A.pdf (last visited June 18, 2025).

 ⁸⁴ United States Food and Drug Administration, ColoSense-P230001 Approval Letter, United States Department of Health and Human Services (May 3, 2024) <u>https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230001A.pdf</u> (last visited June 18, 2025).
 ⁸⁵ United States Food and Drug Administration, 510(k) Substantial Equivalance Determination Decision Summary: Instant-View-PLUS Immunochemical Fecal Occult Blood Test, (Feb. 15, 2018)

https://www.accessdata.fda.gov/cdrh_docs/reviews/K173212.pdf (last visited June 18, 2025). ⁸⁶ United States Food and Drug Administration, Cologuard Plus – P230043 Approval Letter, (Oct. 3, 2024)

⁸⁷ United States Food and Drug Administration, Cologuard – P130017 Approval Letter, United States Department of Health and Human Services, (Aug. 11, 2014) <u>https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017A.pdf</u> (last visited June 18, 2025).

⁸⁸ American Cancer Society, *Biomarker Tests and Cancer Treatment,* available <u>Biomarker Tests and Cancer Treatment |</u> <u>American Cancer Society</u> (last visited June 18, 2025).

⁸⁹ American Cancer Society, *Biomarker Tests and Cancer Treatment,* available <u>Biomarker Tests and Cancer Treatment |</u> <u>American Cancer Society</u> (last visited June 18, 2025).

⁹⁰ S. <u>409.905(9), F.S.</u>

⁹¹ Rule 59G-4,087, Evaluation and Management Services Coverage Policy, (Effective Jun. 29, 2016) <u>https://ahca.mvflorida.com/medicaid/rules/adopted-rules-service-specific-policies</u> (last visited June 18, 2025).

Medicaid covers medically necessary diagnostic laboratory procedures ordered by a licensed physician or other licensed practitioner of the healing arts for a Medicaid recipient in a federally certified laboratory.⁹² Florida Medicaid laboratory services provide clinical testing of bodily fluids, tissues, or other substances. Laboratory services rendered to an eligible recipient must not be duplicative of another service and comply with the American Medical Association's Current Procedural Terminology and the Florida Medicaid fee schedule.⁹³

The Medicaid Laboratory Services Coverage Policy⁹⁴ delineates the reimbursement policy for genetic and biomarker testing, including:

- *Clinical cytogenetics* which studies a patient's chromosomes looking for changes, including broken, rearranged, or extra chromosomes which may be the sign of a disease or a condition.⁹⁵
- *Genetic carrier screening* occurs when an individual is thinking of starting a family and wants to know if he or she carries a specific gene, usually an inherited genetic condition; or testing a sibling for an inherited trait.⁹⁶
- *Histocompatibility* is a chromosomal complex and relates to the compatibility or incompatibility of tissue types for tissue grafting, and also influences an individual's resistance and susceptibility to a range of infectious diseases.⁹⁷ Biomarker testing is conducted primarily for donor matching.⁹⁸
- Whole genome sequencing is a process in which an individual's chromosomal DNA is sequenced or put in order to identify variants or mutations among chromosomes.⁹⁹ Targeted sequencing may be used for disease identification and treatment options.

Medicaid specifically excludes testing for multiple organ and disease panels that contain duplicate components or are repeat tests as a result of provider error.¹⁰⁰ Medicaid managed care plans have the flexibility to cover services above and beyond Medicaid Coverage Policies, but they may not be more restrictive.¹⁰¹

Biomarker Testing Services

As of 2024, current law requires Medicaid to cover biomarker testing services for diagnosis, treatment, appropriate management, and ongoing monitoring of a recipient's disease or condition, provided the available medical and scientific evidence indicates that the specific biomarker test provides clinical utility to the recipient. However, current law does not expressly authorize traditional Medicaid and Medicaid managed care to cover biomarker testing when its purpose is for screening services.¹⁰²

⁹² S. 409.905(7), F.S.

 ⁹³ Rule 59G-4.190, *Laboratory Services and Coverage* Policy (Jan. 2024; Effective Apr. 3, 2024), available at <u>Reference Material</u> <u>Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org)</u> (last visited June 18, 2025).
 ⁹⁴ Rule 59G-4.190, *Laboratory Services and Coverage* Policy (Jan. 2024; Effective Apr. 3, 2024), available at <u>Reference Material</u> <u>Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org)</u> (last visited June 18, 2025).
 ⁹⁵ National Human Genome Research Institute, *Cytogenetics* (updated Mar. 22, 2024), available at

https://www.genome.gov/genetics-glossary/Cytogenetics (last visited June 18, 2025).

⁹⁶ National Human Genome Research Institute, *Carrier Screening* (updated Mar. 22, 2024), available at

https://www.genome.gov/genetics-glossary/Carrier-Screening (last visited June 18, 2025).

⁹⁷ Dustin J. Penn, Major Histocompatibility Complex, Encyclopedia of Life Sciences (2002), available at

https://www.researchgate.net/publication/228038374 Major Histocompatibility Complex MHC (last visited June 18, 2025). ⁹⁸ Eric Epierings, Katharina Fleischhauer, *Chapter 9: Histocompatibility*, National Library of Medicine, The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies (2019), available at https://www.researchgate.net/publication/228038374 Major Histocompatibility, National Library of Medicine, The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies (2019), available at

https://www.ncbi.nlm.nih.gov/books/NBK553927/ (last visited June 18, 2025).

⁹⁹ van El CG, Cornel MC, et al, ESHG Public and Professional Policy Committee. *Whole-genome sequencing in health care. Recommendations of the European Society of Human Genetics,* Eur J Hum Genet. 2013 Jun;21 Suppl 1(Suppl 1):S1-5, available at . <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3660957/</u> (last visited June 18, 2025).

¹⁰⁰ Rule 59G-4.190, *Laboratory Services and Coverage* Policy (January 2024; Effective April 3, 2024), available at <u>Reference</u> <u>Material Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org)</u> (last visited June 18, 2025).

 ¹⁰¹ Agency for Health Care Administration, *2024 Agency Legislative Bill Analysis – SB 964/HB* 885, pp. 2 (January 17, 2024) (on file with the Select Committee on Health Innovation).
 ¹⁰² S. 409.906(29), F.S.

According to AHCA, Medicaid currently covers colorectal cancer screening tests in general. However, it is unclear whether Medicaid covers blood-based biomarker colorectal cancer screening tests.¹⁰³

Biomarker Testing Billing Codes

The American Medical Association's Current Procedural Terminology (CPT) codes offer physicians and health care practitioners a uniform language for coding medical services and procedures to streamline reporting, with the intention to increase accuracy and efficiency. Proprietary Laboratory Analysis (PLA) codes are a subset of CPT codes, which describe the proprietary clinical laboratory analyses that certain laboratories can provide.¹⁰⁴

Medicaid Enrollment for Permanently Disabled Individuals

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by AHCA and financed by federal and state funds.¹⁰⁵ AHCA delegates certain functions to other state agencies, including DCF, the Agency for Persons with Disabilities (APD), the Department of Health (DOH), and the Department of Elderly Affairs (DOEA).

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds. 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.¹⁰⁶ States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, adult dental services, and dialysis.¹⁰⁷

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 (HHS) 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." Section 1115 of the Social Security Act allows states to implement demonstrations of innovative service delivery systems that improve care, increase efficiency, and reduce costs. These laws allow HHS to waive federal requirements to expand populations or services, or to try new ways of service delivery.

Florida operates under 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. Florida also has waivers under Sections 1915(b) and (c) of the Social Security Act to operate the SMMC Long-Term Care (LTC) program and the Development Disabilities Individual Budgeting (iBudget) Waiver.¹⁰⁸

Federal Medicaid law establishes coverage for institutional care, such as nursing home care and residential institutions for people with developmental disabilities, but does not allow federal dollars to be spent on alternatives to such care. Those alternatives include home- and community-based services (HCBS) designed to keep people in their homes and communities instead of going into an institution when they need higher levels of

¹⁰⁴ American Medical Association, "CPT overview and code approval," <u>https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval#what-is-a-cpt-code</u> (last visited June 18, 2025).

¹⁰³ Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1335 Fiscal Questions, (Mar. 25, 2025), on file with the Health and Human Services Committee. The Statewide Medicaid Managed Care plans also waive copayments and coinsurance requirements for all services under their expanded benefits.

¹⁰⁵ Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725) (2016).

¹⁰⁶ S. <u>409.905, F.S.</u>

¹⁰⁷ S. <u>409.906, F.S.</u>

¹⁰⁸ S. <u>409.964, F.S.</u>

care. This federal spending limitation creates a bias toward institutional care, and toward acute care, rather than allowing the non-acute supports that prevent institutionalization.

Long-Term Care Home and Community-Based Services Program

Florida obtained a federal waiver to allow the state Medicaid program to cover HCBS long-term care services for elders and people with disabilities,¹⁰⁹ to prevent admission into a nursing home.

iBudget Home and Community-Based Services Waiver Program

AHCA oversees the Medicaid HCBS program for individuals with specified developmental disabilities through a federal waiver administered by APD, known as iBudget, the purpose of the waiver is to:¹¹⁰

- Promote and maintain the health and welfare of individuals with developmental disabilities;
- Provide medically necessary supports and services to delay or prevent institutionalization; and
- Foster the principles of self-determination as a foundation for services and supports.

The iBudget provides HCBS to eligible persons with developmental disabilities living at home or in a home-like setting. Eligible diagnoses include disorders or syndromes attributable to intellectual disability, cerebral palsy, autism, spina bifida, Down syndrome, Phelan-McDermid syndrome, or Prader-Willi syndrome. The disorder must manifest before the age of 18, and it must constitute a substantial handicap that can reasonably be expected to continue indefinitely.¹¹¹

The iBudget program allocates available funding to clients through an algorithm, providing each one an established budget with the flexibility to choose from the authorized array of services that best meet their individual needs within their community.¹¹²

Medicaid Eligibility

Medicaid eligibility in Florida is determined either by DCF or the Social Security Administration (SSA) for Supplemental Security Income (SSI) recipients. Since Medicaid is designed for low-income individuals, Medicaid eligibility is based on an evaluation of the individual's income and assets.

Section 1614(3) of the Social Security Act provides that an individual shall be considered to be disabled if they are unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve months. Further, an individual under the age of 18 shall be considered disabled if that individual has a medically determinable physical or mental impairment, which results in marked and severe functional limitations, and which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.

Under Florida's Medicaid State Plan, permanent and total disability is a physical or mental condition of major significance which is expected to continue throughout the lifetime of an individual and is not expected to be removed or substantially improved by medical treatment. It is expected to continue for a prolonged period of disability and the eventual prognosis may be indefinite. Total disability exists when the permanent impairment, or combination of permanent impairments, substantially precludes the individual from engaging in a useful occupation.

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<sup>111</sup> S. <u>393.063(11), F.S.</u>
<sup>112</sup> S. 393.0662(1), F.S.
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SUMMARY

¹⁰⁹ S. <u>409.979, F.S.</u> Individuals 65 years of age or older and in need of nursing facility level of care; or 18 years of age or older and eligible for Medicaid by reason of a disability and in need of nursing facility level of care.

¹¹⁰ Florida Medicaid Developmental Disabilities Individual Budgeting Waiver Services Coverage and Limitations Handbook, AHCA (May 2023), available at

https://apd.myflorida.com/ibudget/docs/iBudget%20Handbook%20with%20ADT%20Redesign%20Final.pdf (last visited June 18, 2025).

DCF uses the same criteria that the SSA uses to determine disability for benefits. If SSA determines an individual is disabled, DCF adopts their disability decision. If an individual does not have a disability decision from SSA, then DCF must obtain a disability determination based on the individual's circumstances.¹¹³

DOEA is responsible for conducting clinical level of care evaluations under the LTC Waiver, while APD is responsible for conducting clinical level of care evaluations under the iBudget Waiver. To be eligible for Medicaid under 1915(c) waivers, the individual must be determined to need the level of care provided by a hospital, nursing home, or intermediate care facility for the developmentally disabled.¹¹⁴ The clinical level of care is determined during an initial evaluation and the individual must be reevaluated at least annually.¹¹⁵

Federal regulations require DCF make a redetermination of eligibility without requiring information from the individual if it is possible to make a redetermination based on reliable information contained in the individual's account or obtained from another state agency or federal agency.¹¹⁶ If DCF is unable to verify the individual's eligibility, they send the recipient a renewal notice, electronically and by mail, requesting the required information to make an eligibility determination.¹¹⁷

Between April 2023 and February 2025, approximately 534 disabled individuals lost their Medicaid coverage¹¹⁸ because they failed to provide information requested by DCF to make an eligibility determination.¹¹⁹ The number of those individuals that would have still been eligible for Medicaid if they would have sent the requested information to DCF is unknown. Over that same period of time, approximately 3,357 disabled individuals lost their Medicaid coverage because they did not meet the income and asset eligibility requirements.¹²⁰

Program of All-Inclusive Care for the Elderly (PACE)

The PACE is a capitated health benefits program¹²¹ authorized by the federal Balanced Budget Act of 1997¹²² that features a comprehensive service delivery system funded by a combination of federal Medicare and state Medicaid financing.¹²³ The PACE is an optional Medicaid benefit, but operates as a three-way agreement between the federal government, a state agency, and a PACE organization.¹²⁴ In Florida, the PACE is a Medicaid long-term care managed care plan option providing comprehensive long-term and acute care services which supports Medicaid and Medicare enrollees who would otherwise qualify for Medicaid nursing facility services.¹²⁵

The PACE provides a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. PACE was created as a way to provide clients, family, caregivers and professional health care providers the flexibility to meet a person's health care needs while continuing to live safely in the community.¹²⁶ The purpose of a PACE program is to provide comprehensive health care services that are designed to:

¹²⁶ *Supra* note 124.

¹¹³ *Supra* note 1.

¹¹⁴ 42 C.F.R., § 441.301(b).

¹¹⁵ 42 C.F.R., § 441.302(c).

¹¹⁶ 42 C.F.R., § 435.916.

¹¹⁷ *Supra* note 1.

¹¹⁸ Includes the following categories of Medicaid that cover disabled populations: Family Related Medicaid; Long-term Care Medicaid; HCBS Waiver Medicaid; Community Hospice Medicaid; and Medicaid for Aged and Disabled (MEDS-AD). ¹¹⁹ Supra note 1.

¹²⁰ Id.

¹²¹ See Centers for Medicare & Medicaid Services, *Capitated Model*, <u>https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-Medicaid-Coordination/Medicare-Medicaid-Coordination-</u>

Office/FinancialAlignmentInitiative/CapitatedModel (last accessed May 3, 2021).

¹²² Pub. L. 105-33. PACE program requirements are codified at 42 USC 1302, 1395, and 1395eee.

¹²³ Services under the PACE program are authorized under Section 1905(a)(26) of the Social Security Act.

¹²⁴ Department of Health and Human Services, Centers for Medicare and Medicaid Services, CMS Manual System: Pub. 100-11 Programs of All-Inclusive Care for the Elderly (PACE) Manual (issued June 9, 2011), <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c01.pdf</u> (last accessed May 3, 2021).

¹²⁵ Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), http://ahca.myflorida.com/docs/PACE_Evaluation_2014.pdf (last accessed May 3, 2021).

- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of and respect for older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
- Preserve and support the older adult's family unit.¹²⁷

In Florida, the PACE is operated cooperatively by the DOEA and the AHCA. DOEA is the operating entity and oversees the participating PACE organizations, while AHCA is formally responsible for maintaining the PACE agreement with the federal government and for Medicaid reimbursement of PACE services. DOEA, AHCA, and the CMS must approve any application for new PACE agreements, as well as any expansion of current PACE organizations.¹²⁸

PACE Organizations

A PACE organization is a not-for-profit, or for-profit private or public entity that is primarily engaged in providing PACE services. For-profit entities operating PACE organizations do so only under federal demonstration authority.¹²⁹ A PACE organization must:

- Have a governing body or a designated person functioning as a governing body that includes participant representation.
- Be able to provide the complete service package regardless of frequency or duration of services.
- Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals.
- Have a defined service area.
- Have safeguards against conflict of interest.
- Have demonstrated fiscal soundness.
- Have a formal participant bill of rights.
- Have a process to address grievances and appeals.¹³⁰

Before being approved to operate and deliver services, PACE organizations are required to provide evidence of the necessary financial capital to deliver the benefits and services, which include a combined adult day care center and primary care clinic, transportation, and full range of clinical and support staff with an interdisciplinary team of professionals.¹³¹

Graduate Medical Education (GME)

GME is an approved component of Medicaid inpatient and outpatient hospital services. If a state Medicaid program opts to cover GME costs, the federal government provides matching funds. Florida opts to fund GME through the Statewide Medicaid Residency Program (SMRP). For fiscal year 2023-2024, the SMRP funded 6,176 residents at 83 location.¹³²

The SMRP allows both hospitals and Federally Qualified Health Centers (FQHC) that are accredited by the Accreditation Council for Graduate Medical Education (ACGME) to qualify for GME funding. In addition to the SMRP, the Legislature has allocated additional funding to GME through the Startup Bonus Program and the Slots for Doctors Program.

https://ahca.myflorida.com/content/download/23217/file/SFY%2023-24%20GME%20SMRP%20Calculation%20Clean.pdf, (last visited June 18, 2025).

¹²⁷ *Supra* note 125.

¹²⁸ Id.

¹²⁹ Sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Balanced Budget Act of 1997 allowed private, for-profit entities to participate in PACE as demonstration projects. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations.

¹³⁰ *Supra* note 7.

¹³¹ *Id*.

¹³² SFY 2023-24 Statewide Medicaid Residency Program Distribution, AHCA, available at

Graduate Medical Education Committee (GMEC)

The GMEC within the AHCA is made up of:

- Three deans, or their designees, from medical schools in this state, appointed by the chair of the Council of Florida Medical School Deans.
- Four members appointed by the Governor, one of whom is a representative of the Florida Medical Association or the Florida Osteopathic Medical Association who has supervised or is currently supervising residents, one of whom is a member of the Florida Hospital Association, one of whom is a member of the Safety Net Hospital Alliance, and one of whom is a physician licensed under ch. 458 or ch. 459, F.S., practicing at a qualifying institution.
- Two members appointed by the Secretary of the Agency for Health Care Administration, one of whom represents a teaching hospital as defined in <u>s. 408.07, F.S.</u>, and one of whom is a physician who has supervised or is currently supervising residents.
- Two members appointed by the State Surgeon General, one of whom must represent a teaching hospital as defined in <u>s. 408.07, F.S.</u>, and one of whom is a physician who has supervised or is currently supervising residents or interns.
- Two members, one appointed by the President of the Senate and one appointed by the Speaker of the House of the Representatives.¹³³

The members of the committee who are medical school deans will serve four-year terms and rotate membership through the medical schools in Florida. Otherwise, members serve four-year terms with the initial terms being three or two years for specified members in order to stagger changes of membership. The GMEC must elect a chair to serve for a one-year term and members are required to serve without compensation but are entitled to reimbursement for per diem.¹³⁴

The committee is required to meet at least twice annually at the call of the chair. Meetings may be conducted electronically with a majority of the members representing a quorum.¹³⁵

Beginning July 1, 2025, the committee is required to submit an annual report to the Governor and the Legislature detailing:

- The role of residents and medical faculty in the provision of health care.
- The relationship of graduate medical education to the state's physician workforce.
- The typical workload for residents and the role such workload plays in retaining physicians in the long-term workforce.
- The costs of training medical residents for hospitals and qualifying institutions.
- The availability and adequacy of all sources of revenue available to support graduate medical education.
- The use of state funds, including, but not limited to, intergovernmental transfers, for graduate medical education for each hospital or qualifying institution receiving such funds.

AHCA is required to provide reasonable and necessary support staff and materials to the committee, to provide the information obtained from the reporting requirements, and to assist the committee in obtaining any other information necessary to produce its report.¹³⁶

Achieved Savings Rebate (ASR)

The ASR Program is an incentive for proper use of state funds in the Statewide Medicaid Managed Care program. The program monitors plans' premium revenues, medical and administrative costs, and income or losses in a

¹³³ <u>s. 409.909(9), F.S.</u>

¹³⁴ Id.

¹³⁵ *Id.*

¹³⁶ Id.

uniform manner.¹³⁷ AHCA is responsible for verifying the ASR for all Medicaid prepaid plans. AHCA is required to contract with independent certified public accountants to conduct compliance audits for the purpose of auditing financial information, including but not limited to: annual premium revenue, medical and administrative costs, and income or losses reported by each prepaid plan, in order to determine and validate the achieved savings rebate.¹³⁸ Prepaid plans are required to make available to the agency and the agency's contracted certified public accountant all books, accounts, documents, files, and information that relate to the prepaid plan's Medicaid transactions.¹³⁹ The certified public accountant submits the completed audit report to the agency, attesting to the achieved savings of the plan. The results of the audit report are dispositive.¹⁴⁰ If a plan reports that its profits exceed a certain percent of revenue (thereby achieving savings for the overall program), the plan must return a portion of the profits (a rebate) to the state.¹⁴¹

The ASR is established by determining pretax income as a percentage of revenues and applying the following income sharing ratios:

- All profit up to five percent of revenue is retained by the plan. Half of the profit above five percent and up to 10 percent of revenue is retained by the plan and the other half refunded to the state. All profit above 10 percent of revenue is refunded to the state. All refunds to the state are transferred to the General Revenue Fund, unallocated.¹⁴²
- Plans may retain an additional one percent of revenue if they meet or exceed quality measures defined by AHCA, including plan performance for managing complex, chronic conditions that are associated with an elevated likelihood of recurring high-cost medical treatments.¹⁴³

The bill was approved by the Governor on June 30, 2025, ch. 2025-204, L.O.F., and became effective on July 1, 2025.

RECENT LEGISLATION:

YEAR	BILL #	HOUSE SPONSOR(S)	SENATE SPONSOR	OTHER INFORMATION
2024	<u>CS/SB 7016</u>		Fiscal Policy	Click or tap here to enter text.
2024	<u>SB 7018</u>		Harrell	Click or tap here to enter text.
2024	<u>CS/SB 7072</u>		Fiscal Policy	Click or tap here to enter text.

¹³⁷ Office of Program Policy Analysis and Government Accountability, AHCA Reorganized to Enhance Managed Care Program Oversight and Continues to Recoup Fee-for-Service Overpayments (Report No. 16-03), available at https://oppaga.fl.gov/Documents/Reports/16-03.pdf (last visited June 18, 2025)
 ¹³⁸ <u>s. 409.967(3)(b), F.S.</u>
 ¹³⁹ <u>s. 409.967(3)(d), F.S.</u>
 ¹⁴⁰ s. 409.967(3)(e), F.S.

¹⁴¹ <u>s. 409.967(3), F.S.</u>
 ¹⁴² <u>s. 409.967(3)(f), F.S.</u>
 ¹⁴³ s. 409.967(3)(g), F.S.

<u>SUMMARY</u>