HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/HB 885 Coverage for Biomarker Testing
SPONSOR(S): Health & Human Services Committee and Select Committee on Health Innovation, Gonzalez Pittman and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 964

FINAL HOUSE FLOOR ACTION: 114 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Pending

SUMMARY ANALYSIS

CS/CS/HB 885 passed the House on February 29, 2024, and subsequently passed the Senate on March 5, 2024.

Biomarker testing is a method of looking for any structure, process, genes, proteins, or other substance in the body that can be measured and provide information about the body or its products and influence or predict the incidence or outcome of disease. It 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. Biomarker testing is not helpful for all diseases, but it can be helpful to show whether certain types of diseases may be likely to grow or spread; whether certain types of treatment may be more likely or unlikely to be helpful; and whether a particular treatment is working.

The bill requires coverage within the state group insurance plan and Medicaid program for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition or to guide treatment. The bill requires enrollees to have access to a clear and convenient process to request authorization for testing through readily accessible websites of the insurer, health plan, and Medicaid program.

The bill requires the Medicaid program to implement this coverage by October 1, 2024, and makes the coverage requirements applicable to state group health insurance policies issued on or after January 1, 2025.

For Medicaid, the bill authorizes the Agency for Health Care Administration to seek federal approval if necessary to implement the coverage. For Medicaid managed care contracts, the bill permits the inclusion of any rate impact of the benefit change in the applicable contracts.

The bill has an indeterminate, insignificant negative fiscal impact on state government.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2024, except for the provisions related to Medicaid, which are effective October 1, 2024.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Biomarker Testing

Biomarker testing is a method of looking for genes, proteins, and other substances in the body that can provide information about diseases, such as cancer.[1] In 1988, the International Programme on Chemical Safety, led by the World Health Organization (WHO) and in coordination with the United Nations and the International Labor Organization, defined a biomarker as "any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease".[2]

An even broader definition of biomarker testing considers not just the incidence and outcome of disease, but also the effects of treatments, interventions, and even unintended environmental exposures, such as to chemicals or nutrients. In its report on the validity of biomarkers in environment risk assessments, the WHO has stated that the true definition of biomarkers includes "almost any measurement reflecting an interaction between a biological system and a potential hazard, which may be chemical, physical, or biological.[3] Biomarker testing is also 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.[4]

Cancer

Biomarker testing is not helpful for every kind of disease, but for cancer, biomarker testing can show:

- Whether the cancer is likely to grow or spread.
- Whether certain types of cancer treatments may be more likely or unlikely to be helpful.
- Whether the cancer treatment is working.[5]

Studies indicate that currently only half of patients with cancer in the United States for whom biomarker testing is recommended receive the testing.[6] More than a quarter of patients who did not receive the recommended biomarker testing reported lack of coverage by insurance or/and high out-of-pocket costs, if testing was covered.[7]

Different biomarker tests help determine the best cancer treatment options. Many tests look for gene changes in the cancer cells, while some measure certain proteins or other kinds of markers. Other tests may look at just a single biomarker or check for many biomarkers at the same time (such as patterns of certain genes or proteins). Some tests look at all of the genes inside cancer cells.[8]

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[1] National Cancer Institute, *Biomarker Testing for Cancer,* Biomarker Testing for Cancer Treatment - NCI (last visited February 6, 2024).
[2] Kyle Strimbu and Jorge Tavel, M.D., *What are biomarkers?* Curr Opin HIV AIDS. 2010 Nov; 5(6): 463–466, available at doi: 10.1097/COH.0b013e32833ed177 (last visited February 6, 2024).
[3] *Id.*
[4] American Cancer Society, *Biomarker Tests and Cancer Treatment,* available Biomarker Tests and Cancer Treatment | American Cancer Society (last visited February 6, 2024).
[5] *Id*.
[6] Chawla A, Peeples M,Li N, Anhorn R, Ryan J,Signorovitch J., *Real-world utilization of molecular diagnostic testing and matched drug therapies in the treatment of metastatic cancers*, *J Med Econ*. 2018; 21:543-552, available at Real-world utilization of molecular diagnostic testing and matched drug therapies in the treatment of metastatic cancers - PubMed (nih.gov) (last visited February 6, 2024).
[7] Improving access to biomarker testing. American Cancer Society Cancer Action Network. Published September 28, 2020, available at Improving Access to Biomarker Testing | American Cancer Society Cancer Action Network (fightcancer.org) (last visited February 6, 2024).
[8] *Supra,* note 4.

Biomarker tests may be done on tumor samples removed during a biopsy or surgery, or on samples of blood or other bodily fluids without being as invasive.[9] For certain types of cancer, biomarker testing is done routinely to assist with treatment decisions. Targeted therapies and immunotherapies may only work for individuals with certain type of cancers.[10] Using cancer as an example, the most common types of cancer for biomarker testing include cancers where there are changes in designated genes for:

- Non-small cell lung cancer;
- Breast cancer;
- Colorectal cancer; and
- Melanoma skin cancer.[11]

Using a sample of a patient's cancer cells, the testing analyzes the cells to identify the specific biomarkers. The lab's report on the biomarkers identifies the treatments that may be helpful against the cancer or the cancer strains identified. Some biomarker tests may require a testing of the patient's healthy cells for comparison to the patient's cancer cells for different mutations.[12]

Biomarker testing can also identify a driver mutation. A driver mutation is a change in the DNA of a cancer cell which can cause a cancer cell to overgrow or cause a normal cell to become a cancer cell. The other type of biomarker identified in testing is an immunotherapy biomarker. An immunotherapy biomarker may be found on the surface of a cancer cell and impacts how the cancer cells interact with the immune system. Knowing the types of biomarkers an individual has aids in the individual's plan of care.[13]

A number of types of biomarker tests for molecularly targeted therapies[14] are in clinical use. These tests may include only a single-gene which guide the use of a single class of therapy to a suite of multiple, but separate, tests for single genes which aide in the use of multiple therapy options in a specific clinical context for something like breast cancer treatment.[15] Multiple-gene panels include additional analytes for other clinical or research purposes, including assessing a patient's secondary response or resistance to targeted therapies, multiplex panel tests, protein express, and whole exome, whole genome, and whole transcriptome sequencing.[16]

Growth in this area of medicine has expanded exponentially. For genome-informed therapy, the number of tests available or eligible for testing since 2018 has increased from 16 percent to 27 percent in 2020.[17] From January 1, 2006, when tracking of such approval began at the federal Food and Drug Administration (FDA), through June 30, 2020, 51 different drugs had been approved for 36 genomic indications covering 18 cancer types.[18]

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[9] *Id.*
[10] *Supra*, note 1.
[11] *Supra*, note 4.
[12] *Id.*
[13] Genentech, *Understanding Biomarkers,* available at Learn About Biomarkers And Biomarker Testing in Advanced Non-Small Cell Lung Cancer | MyCareRoadMap By Genentech (last visited February 6, 2024).
[14] Laurene A, Graig, et al, *Biomarker Tests for Molecularly Targeted Therapies, Institute of Medicine, The Nat'l Academies of Science, Engineering &* Medicine (2016), available at Biomarker Tests for Molecularly Targeted Therapies. Key to Unlocking Precision Medicine (nih.gov) (last visited March 22, 2024). A "molecularly targeted therapy" is defined as a therapy created to exploit the known "driver" molecular biomarkers as the therapeutic targets in diseases such as oncology.
[15] Laurene A, Graig, et al, *Biomarker Tests for Molecularly Targeted Therapies, Institute of Medicine, The Nat'l Academies of Science, Engineering & Medicine (2016), available at* Biomarker Tests for Molecularly Targeted Therapies. Key to Unlocking Precision Medicine (nih.gov) (last visited February 6, 2024).
[16] *Id.*
[17] Genomic testing for targeted oncology drugs: hopes against hype, Editorial, *Annals of Oncology*, (Vol. 32, Iss.7, 2021), available at Genomic testing for targeted oncology drugs: hopes against hype (annalsofoncology.org) (last visited February 6, 2024).
[18] A. Haslam, M.S. Kim, & V. Presad, *Updated Estimates of Eligibility for and Responses to Genome Targeted Oncology Drugs Among US Cancer Patients; Annals of Oncoloy* (Vol. 32, Issue 7, July 2021; 926:943), available at Updated estimates of eligibility for and response to genome-targeted oncology drugs among US cancer patients, 2006-2020 - Annals of Oncology (last visited February 6, 2024).

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.[19]

Waiting for results from biomarker tests before determining treatment options can provide a patient and his or her providers more information on which to make decisions. Results from testing can take up to four weeks or longer to receive.[20] A patient may also have biomarker testing more than once during treatment to determine the efficacy of a treatment or if other options need to be considered.[21]

In 2020, the FDA approved two liquid biopsy tests that help guide treatment therapies for individuals with any solid tumor cancer, but not those with a blood cancer. These two approved tests can check for multiple cancer related mutations and are considered less invasive and quicker than the typical needle biopsy.[22] One test, Guardant360 CDX, checks for changes in more than 60 genes, while the other approved test, FoundationOne Liquid CDx, can identify changes in more than 300 genes.[23] Medicare does provide coverage for two FDA-approved tests, but coverage by private insurance companies for these same tests is not consistent among insurers.

Non-Cancer Conditions

Biomarker testing occurs in other diagnostic and treatment areas other than cancer. Scientists and health care providers have used biomarker testing for advances in the diagnosis, treatment, and management of acute respiratory diseases, cardiovascular disease, asthma. Cystic fibrosis, and Duchenne muscular dystrophy, as other examples.[24] Testing allows a patient's health care team to classify the disease by any subset, better predict responses to available drugs or therapies, and provide early detection and treatment of any advancement of the disease or complication as is done with cancer patients.[25] Researchers have argued that biomarker testing for molecularly targeted therapies could have long term cost savings through the avoidance of non-beneficial treatments in specific patients.[26]

Costs of Biomarker Testing

Cost Per Test

The average allowed unit cost per test is the negotiated rate between the providers and the payers before any member cost sharing. A 2022 study by Milliman using its proprietary database noted that utilization of current biomarker benefits nationally varied in the commercial market based on the plan

[19] *Supra*, note 4.
[20] LUNGevity, *Biomarker testing can help you get the best treatment for your lung cancer,* 353b8753a58e4ebaae940e2d4b95ca49 (d2zd6ny1q7rvh6.cloudfront.net) (last visited February 6, 2024).
[21] *Id.*
[22] National Cancer Institute, *FDA Approves Cancer Test Which Can Help Guide Cancer Treatment (October 15, 2020)* FDA Approves Blood Tests That Can Help Guide Cancer Treatment - NCI (last visited February 6, 2024).
[23] Id.
[24] National Institute of Environmental Health Sciences, *Biomarkers,* available at https://www.niehs.nih.gov/health/topics/science/biomarkers (last visited March 20, 2024).
[25] Graig, L.A., Phillips, J.K., Moses, HL, ed., *Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine,* Committee on Policy Issues in the Clinical Development and Use of Biomarkers for Molecularly Targeted Therapies; Board of Health Care Services, Institute of Medicine; National Academies of Sciences, Engineering and Medicine (Washington, D.C.; National Academies Press, U.S.), 2016 June 30, available at https://www.ncbi.nlm.nih.gov/books/NBK379335/ (last visited March 20, 2024).
[26] *Id.*

type with higher utilization in the individual market than in the large group or small group markets.[27] However, the average allowed unit cost per test remained consistent at $225. For Medicaid, utilization performed similarly to the commercial market; however, the average allowed unit cost per test for Medicaid was $80.[28]

Another study, which used commercial claims and administrative data from 90 million covered lives, reported the total payer lifetime costs per patient for all biomarker testing ranged from $128 to $452 across all tumor types. The payer costs among these patients varied by the type of payer with the mean being the highest among consumer directed health plans and preferred provider organizations, and the lowest found with point of service plans.[29]

Patient Out of Pocket Costs

Using the same commercial claims data as above, for insured patients with metastatic lung or thyroid cancer, the median lifetime patient out-of-pocket costs for the testing for most patients was $0. The exception was for consumer-driven health plans which had a median patient out of pocket cost of $12 for thyroid and $10 for metastatic lung testing.[30]

Since 2019, more than 26 million people have purchased a direct to consumer genetic test from one of the four largest testing companies.[31] Costs vary by type of testing. For example, one FDA-approved test for direct sale to patients can identify cancer-associated alterations in 324 genes in any type of solid tumor.[32] Different levels of screening tests can be ordered by a patient directly online or by a patient's health care provider for $299 - $350,the cost of the test, which does not include the cost of analysis or review by a health care practitioner.[33]

For new cancer treatments, costs may be covered as part of clinical trials. If an individual participates in a clinical trial, the company testing a new treatment may cover the testing costs as part of the individual's participation.[34] Increasingly, clinical trials report the enrollment of individuals based on the specific genetic mutation or alteration and not which organ the cancer originated from.[35]

State Employee Health Plan Coverage of Biomarker Testing

The Department of Management Services (DMS) through the Division of State Group Insurance (DSGI) under the authority of section 110.123, F.S., administers the state group health insurance program (Program) for state employees, retirees, and their families. The Program is a cafeteria plan managed consistent with section 125 of the Internal Revenue Code.[36] To administer the program, DSGI contracts

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[27] Gabriela Dieguez and Jennifer Carioto, Milliman White Paper, *The landscape of biomarker testing coverage in the United States (February 2022)* available at https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx (last visited March 22, 2024).
[28] *Id*.
[29] Lisa M. Hess, et al., *Costs of biomarker testing among patients with metastatic lung or thyroid cancer in the USA: a real-world commercial claims database study,* J Med Econ 2023 Jan-Dec;26(1):43-50., available at Costs of biomarker testing among patients with metastatic lung or thyroid cancer in the USA: a real-world commercial claims database study - PubMed (nih.gov) (last visited March 22, 2024).
[30] *Id.*
[31] Panacer KS. Ethical Issues Associated With Direct-to-Consumer Genetic Testing. Cureus. 2023 Jun 3;15(6):e39918. doi: 10.7759/cureus.39918. PMID: 37404400; PMCID: PMC10317585, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10317585/ (last visited March 25, 2024).
[32] National Cancer Institute, *Genomic Profiling Tests Cleared by FDA Can Help Guide Cancer Treatment, Clinical Trial Enrollment (December 21, 2017)*, https://www.cancer.gov/news-events/cancer-currents-blog/2017/genomic-profiling-tests-cancer (last visited February 6, 2024).
[28] *Id*.
[34] *Supra*, note 4.
[35] National Cancer Institute, *Genomic Profiling Tests Cleared by FDA Can Help Guide Cancer Treatment, Clinical Trial Enrollment (December 21, 2017)* available at FDA Approves Two Genomic Profiling Tests for Cancer - NCI (last visited February 6, 2024).
[36] A section 125 cafeteria plan is a type of employer offered, flexible health insurance plan that provides employees a menu of pre-tax and taxable qualified benefits to choose from, but employees must be offered at least one taxable benefit such as cash, and one qualified benefit, such as a Health Savings Account.

with third party administrators for self-insured plans, a fully insured HMO, and a pharmacy benefits manager for the state employees' self-insured prescription drug program, pursuant to s. 110.12315, F.S.

The Program delivers benefits through competitively bid contracts with health insurers, health maintenance organizations, and third party administrators. The current benefits and premium rates for the plan year of January 1, 2024 through December 31, 2024 are established in these contracts and the state's General Appropriations Act. Any additional statutory changes in state employee benefits require a contract amendment to modify those benefits.

A review of the 2024 state group health insurance plans' online member benefit handbooks, medical policy guidelines, and genetic testing guidelines indicate that biomarker testing is covered within the Program in a non-uniform manner, in limited circumstances and with test-specific conditions. Which tests are covered varies by health plan. Each plan has its own medical policy guidelines and reviews independently whether a particular biomarker test meets its medical necessity requirements taking into consideration expert medical opinions and published research in respected scientific journals. A biomarker test may be covered under a plan's medical guidelines; however, coverage may be limited to those members who may have a family history of that disease or exhibit specific symptoms of the disease.

Additionally, all of the contracted state group health insurance plans include a general exclusionary coverage statement which precludes coverage for any testing considered experimental or investigational, unless the testing falls under an allowable clinical trial.[37]

Medicaid Coverage of Biomarker Testing

Florida Medicaid covers biomarker testing under s. 409.905(7), F.S., as a mandatory Medicaid service under independent laboratory services.[38] Eligible providers are reimbursed for covered biomarker testing services listed under Rule 59G-4.190, F.A.C., the Laboratory Services and Coverages Policy and paid through Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules.

The services provided to the eligible recipient must be medically necessary, not duplicative of another service, and meet the criteria of the policy. To meet the criteria, the service must be provided to the eligible recipient in accordance with the American Medical Association's Current Procedural Terminology and the Florida Medicaid fee schedule.[39]

The Medicaid Laboratory Services Policy[40] covers reimbursement for genetic and biomarker testing currently, including services for:

- *Clinical cytogenetics* which studies a patient's chromosomes looking for changes, including broken, re-arranged, or extra chromosomes which may be the sign of a disease or a condition.[41]
- *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.[42]
- *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

[37] Department of Management Services, *My Benefits – Health Plans in Your Area,* available at Health Plans in Your Area / Health Insurance Plans / Health - MyBenefits / Department of Management Services (myflorida.com) (last viewed January 23, 2024).
[38] S. 409.905(7), F.S.
[39] Rule 59G-4.190, *Laboratory Services and Coverage* Policy (January 2024; Effective April 3, 2024), available at Reference Material Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org) (last visited March 22, 2024).
[40] *Id.*
[41] National Human Genome Research Institute, *Cytogenetics (updated March 22, 2024),* available at https://www.genome.gov/genetics-glossary/Cytogenetics (last visited March 25, 2024).
[42] National Human Genome Research Institute, *Carrier Screening (updated March 22, 2024),* available at https://www.genome.gov/genetics-glossary/Carrier-Screening (last visited March 25, 2024).

to a range of infectious diseases.[43] Biomarker testing is conducted primarily for donor matching.[44]
- *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.[45] Targeted sequencing may be used for disease identification and treatment options.

Testing is specifically excluded for multiple organ and disease panels that contain duplicate components or are repeat tests as a result of provider error.[46] Medicaid managed care plans have the flexibility to cover services above and beyond AHCA coverage policies, but they may not be more restrictive than AHCA policy.[47]

Medicare National and Local Coverage Determinations

A National Coverage Determination (NCD)[48] is a decision by the federal Centers for Medicare and Medicaid Services (CMS) of whether Medicare will pay for a specific item or service.[49] If an item or service is not currently covered, a formal request for an NCD can be initiated by an outside party or CMS staff. An NCD is binding on all fiscal intermediaries, Medicare administrative contractors (MACs) and carriers, quality improvement organizations, administrative law judges, attorney adjudicators, and the Medicare Appeals Council.[50]

A Local Coverage Determination[51] is a decision by an individual fiscal intermediary or MAC whether or not to provide coverage for a particular service or item on a contractor-wide basis that would not otherwise be covered under Medicare in accordance with section 1862(a)(1)(A) of the Social Security Act.[52]

Effect of the Bill

State Employee Health Plan Coverage of Biomarker Testing

CS/CS/HB 885 requires all policies issued under the Program on or after January 1, 2025, to provide coverage of biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition if the medical and scientific evidence indicated that the biomarker testing provides clinical utility to the enrollee.

Under the bill, such medical and scientific evidence includes, but is not limited to:
- A labeled indication for a test approved or cleared by the FDA;
- An indicated test for a drug approved by the FDA;

[43] 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 March 25, 2024).
[44] 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.ncbi.nlm.nih.gov/books/NBK553927/ (last visited March 25, 2024).
[45] 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 . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3660957/ (last visited March 25, 2024).
[46] *Supra,* note 48.
[47] Agency for Health Care Administration, *2024 Agency Legislative Bill Analysis – SB 964/HB* 885 (January 17, 2024) (on file with the Select Committee on Health Innovation).
[48] 42 U.S.C.§1395y(l)(6)(A). The Social Security Act provides the definition for National Coverage Determination as determination by the Secretary (of Health and Human Services) with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Act.
[49] 42 CFR § 405.1060; *See also* Centers for Medicare and Medicaid Services, *Medicare Coverage Determination Process,* available at https://www.cms.gov/medicare/coverage/determination-process (last visited March 22, 2024).
[50] 42 CFR §405.1060.
[51] 42 U.S.C.§1395ff(f)(2)(B) (2024).
[52] 42 U.S.C.§1395y(a)(1)(A)(2024). The Social Security Act provides that no payment shall be made for any items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

- An NCD made by CMS or an LCD made by a MAC; or
- A nationally recognized clinical practice guideline developed by an independent organization or medical professional society using transparent methodology and reporting structure, and with a conflict of interest policy.

The bill expressly provides that the coverage requirements for biomarker testing services do not include testing for screening purposes.

Medicaid Coverage of Biomarker Testing

The bill amends s. 409.906, F.S., to add biomarker testing services as an optional Medicaid service, if medical and scientific evidence indicate that biomarker testing for the diagnosis, treatment, and appropriate management of a Medicaid recipient's disease provides clinical utility to the Medicaid recipient.

Medicaid managed care plans must provide coverage for biomarker testing in the same manner and scope as Medicaid provides to other medically necessary treatments.

The bill further authorizes AHCA to seek federal approval, if necessary to implement the coverage requirement.

Patient and Provider Testing Authorization Process

The bill requires each state group health insurance plan to provide a clear and convenient process for enrollees to request authorization for biomarker testing. The process must be readily accessible to providers and enrollees and providers online.

Medicaid and the Medicaid managed care plans must provide a Medicaid recipient and his or her providers easy access to a clear and convenient authorization process for biomarker testing. If the recipient is enrolled in managed care, the managed care plans must make the process readily available on its website.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2024, except for the provisions related to Medicaid, which are effective October 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill will have an indeterminate, insignificant negative fiscal impact on the Department of State Group Insurance. Based on denied claims for biomarker testing from prior years, the potential impact may range from $0 to $1.6 million annually.[53]

The bill has no impact on AHCA, as biomarker testing is already a covered service under Florida Medicaid.[54]

[53] Department of Management Services, *2024 Agency Legislative Bill Analysis: CS/HB 885* (February 5, 2024), (on file with the House Appropriations Committee).
[54] *Supra*, note 41.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.