The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL:	SB 964
INTRODUCER:	Senator Calatayud
SUBJECT:	Coverage of Biomarker Testing
DATE:	February 5, 2024
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Pre-meeting**
2.			AHS	
3.			FP	

I. Summary:

SB 964 requires Florida's Medicaid program, certain health insurance policies, and health maintenance organization (HMO) contracts to provide coverage for biomarker testing for the diagnosis, treatment, management, and ongoing monitoring of disease or condition of a enrollee, insured, or subscriber to guide treatment decisions when the following conditions are met:

- Such testing provides clinical utility to the insured or subscriber; and
- The testing is demonstrated by medical and scientific evidence, including but not limited to specified criteria in the bill.

Biomarker testing is a method to look for genes, proteins, and other substances (biomarkers or tumor markers) that can provide information about cancer and other conditions. Biomarker testing is an important part of precision medicine, also known as personalized medicine, which is an approach to medical care in which disease prevention, diagnosis, and treatment are tailored to the genes, proteins, and other substances that are unique to a patient. Such testing may significantly improve health outcomes and prolong patient survival, particularly for those with advanced forms of cancer.

The bill may have a significant operational and fiscal impact on the Medicaid Program. The impact on the Division of State Group Insurance is unknown.

The bill has an effective date of July 1, 2024.

II. Present Situation:

Biomarkers[1] and Tumor Markers[2]

A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. A biomarker is also called molecular marker and a signature molecule. Biomarker testing is a method to look for genes, proteins, and other substances (biomarkers or tumor markers) that can provide information about cancer and other conditions.

A tumor marker is anything present in or produced by cancer cells or other cells of the body in response to cancer or certain benign (noncancerous) conditions that provides information about a cancer, such as how aggressive it is, what kind of treatment it may respond to, or whether it is responding to treatment.

Tumor markers have traditionally been proteins or other substances that are made at higher amounts by cancer cells than normal cells. These can be found in the blood, urine, tumors, or other tissues or bodily fluids of some patients with cancer. Increasingly, however, genomic markers (such as tumor gene mutations, patterns of tumor gene expression, and nongenetic changes in tumor DNA) are being used as tumor markers. These markers are found both in tumors themselves and in tumor fragments shed into bodily fluids. Many different tumor markers have been characterized and are in clinical use.[3] Some are associated with only one type of cancer, whereas others are associated with multiple cancer types.

Application of Tumor Markers in Cancer Care[4]

Tumor markers that indicate whether someone is a candidate for a particular targeted therapy[5] are sometimes referred to as biomarkers for cancer treatment. Tumor markers can provide a wide variety of information that is important for cancer care, such as:

- Helping to diagnose cancer. However, having an elevated level of a tumor marker does not mean that someone has cancer. Noncancerous conditions can sometimes cause an increase in the level of a tumor marker. In addition, not everyone with a particular type of cancer will have a higher level of a tumor marker associated with that cancer. Therefore, measurements of tumor markers are usually combined with the results of other tests, such as biopsies or imaging, to diagnose cancer.
- The type of cancer.

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[1] Biomarker Testing for Cancer Treatment - NCI (last visited Jan. 25, 2024).
[2] Tumor Markers - NCI (cancer.gov) (last visited Jan. 28, 2024).
[3] Tumor Marker Tests in Common Use - NCI (cancer.gov) (last visited Jan. 24, 2024).
[4] *Supra* at 2.
[5] This is a type of treatment that uses drugs or other substances to target specific molecules that cancer cells need to survive and spread. Targeted therapies work in different ways to treat cancer. Some stop cancer cells from growing by interrupting signals that cause them to grow and divide, stopping signals that help form blood vessels, delivering cell-killing substances to cancer cells, or starving cancer cells of hormones they need to grow. Other targeted therapies help the immune system kill cancer cells or directly cause cancer cell death. Most targeted therapies are either small-molecule drugs or monoclonal antibodies. Also called molecularly targeted therapy. *See* Definition of targeted therapy - NCI Dictionary of Cancer Terms - NCI (last visited Jan. 27, 2024).

- The stage of the cancer.
- An estimate of prognosis.
- Determination of what treatment may be effective. Biomarkers are generally measured in samples of tumor tissue. However, tumors can shed cells or bits of biological material into blood, and these can be measured by tests called liquid biopsies.
- How well the treatment is working. Periodic measurements of a marker made while someone is undergoing treatment can indicate whether the tumor is responding to treatment.
- Whether cancer has returned. Measuring tumor markers periodically after treatment has ended may be used to check for recurrence.

Types of Tumor Marker Tests

A number of tumor marker tests are currently being used for a wide range of cancer types.[6] Many tumor marker tests are conducted by commercial and academic laboratories. Sometimes cancer centers use a tumor marker test developed within a single clinical laboratory to meet a specific medical need. All tumor markers are tested in laboratories that meet standards set by the Clinical Laboratory Improvement Amendments program.[7]

State Regulation of Insurance

Office of Insurance Regulation

In Florida, the Office of Insurance Regulation (OIR) licenses and regulates insurers, HMOs, and other risk-bearing entities.[8] To operate in Florida, an insurer or HMO must obtain a certificate of authority from the OIR.[9] The agency regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Prior to receiving a certificate of authority[10] from the OIR, an HMO must receive a Health Care Provider Certificate from the agency. As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[11]

Florida's Medicaid Program

Administration of the Program

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act (SSA). This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare and Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other

[6] Tumor Marker Tests in Common Use - NCI (cancer.gov) (last visited Jan. 23, 2024).
[7] Clinical Laboratory Improvement Amendments (CLIA) | CDC (last visited Jan. 23, 2024).
[8] Section 20.121(3)(a)1., F.S.
[9] Section 641.21(1), F.S.
[10] Sections 624.401 and 641.49, F.S.
[11] Section 641.495, F.S.

administrative and organizational requirements. State Medicaid programs may request a formal waiver of the requirements codified in the SSA. Federal waivers give states flexibility not afforded through their Medicaid state plan.

In Florida, most Medicaid recipients receive their services through a managed care plan (Plan) contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: Managed Medical Assistance (MMA), Long-Term Care (LTC), and Dental. Florida's SMMC program benefits are authorized through federal waivers and are specifically required by the Florida Legislature in s. 409.973 and 409.98, F.S.

Mandatory Medicaid Coverage for Biomarker Testing
Currently, Florida fee for service Medicaid and SMMC covers biomarker testing under s. 409.905(7), F.S., Mandatory Medicaid services, Independent Laboratory Services. Florida Medicaid reimburses eligible providers for biomarker testing services in accordance with Rule 59G-4.190, F.A.C., the Laboratory Services and Coverage Policy, and Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules. An eligible recipient must be enrolled in the Florida Medicaid program on the date of service, and the services provided must be determined medically necessary, not duplicative of another service, and meet the criteria of the policy. When determining coverage or if it is appropriate to add a code to a FFS Medicaid fee schedule, the Agency considers clinical and practice guidelines as well as costs and maintaining budget neutrality.

The SMMC plans have the flexibility to cover services above and beyond the Agency's coverage policies, but they may not be more restrictive than Agency policy.

Medically Necessary or Medical Necessity.[12] Under Florida's Medicaid program, for a medical or allied care, goods, or services furnished or ordered to be considered medically necessary or a medical necessity, it must meet the following conditions:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
- Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs.
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational.
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.
- The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.
- Medically necessary or medical necessity for inpatient hospital services requires that those services furnished in a hospital on an inpatient basis could not, consistent with the provisions

[12] Agency for Health Care Administration, Florida Medicaid, Definitions Policy (Aug. 2017) Definitions of commonly used terms that are applicable to all sections of Rule 59G, F.A.C., unless otherwise specified.

of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient facility of a different type.

Federal and State Insurance Coverage for Biomarker Testing

In 2020 and 2022, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination[13] and local coverage determination[14] that increased access to comprehensive biomarker testing and next-generation sequencing for Medicare beneficiaries.[15] Since 2021, some states have enacted laws mandating coverage of testing, diagnosis, treatment, management, or monitoring of a medical condition, including the following states:

- Louisiana Senate Bill 84 requires broad health insurance coverage for genetic and molecular testing for cancer only.[16]
- Illinois House Bill 1779 requires state-regulated insurance and managed care plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[17]
- Arizona House Bill 2144 requires health insurance coverage for biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[18]
- Rhode Island Senate Bill 2201 requires state-regulated individual and group health insurance plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[19]

Recent Studies on the Cost of Biomarker Testing

A 2022 study found the addition of biomarker testing (liquid biopsy) for non-small cell lung cancer resulted in incremental cost savings of $3,065 per patient compared to tissue biopsy alone. Increased detection of actionable alterations, using liquid biopsy, was also associated with more patients being treated with targeted therapy. Major drivers of cost-effectiveness were drug acquisition costs and prevalence of actionable alterations.[20]

A 2018 study, found that biomarker testing for non-small cell lung cancer, instead of single-gene testing, decreased expected testing procedure related costs to the health plan payer by $24,651. First-line and maintenance treatment costs increased by $842,205, offset by a $385,000 decrease

[13] NCD - Next Generation Sequencing (NGS) (90.2) (cms.gov) (last visited Jan. 20, 2024).
[14] LCD - Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810) (cms.gov) (last visited Jan 20, 2024).
[15] State Legislation Requiring Coverage of Biomarker Testing Gains Momentum (accc-cancer.org) (Sep. 30, 2022) (last visited Jan. 24, 2024).
[16] LA SB84 | 2021 | Regular Session | LegiScan (last visited Jan. 24, 2024).
[17] IL HB1779 | 2021-2022 | 102nd General Assembly | LegiScan (last visited Jan. 24, 2024).
[18] AZ HB2144 | 2022 | Fifty-fifth Legislature 2nd Regular | LegiScan (last visited Jan. 24, 2024).
[19] RI S2201 | 2022 | Regular Session | LegiScan (last visited Jan. 24, 2024).
[20] Ezeife DA, Spackman E, Juergens RA, Laskin JJ, Agulnik JS, Hao D, Laurie SA, Law JH, Le LW, Kiedrowski LA, Melosky B, Shepherd FA, Cohen V, Wheatley-Price P, Vandermeer R, Li JJ, Fernandes R, Shokoohi A, Lanman RB, Leighl NB. The economic value of liquid biopsy for genomic profiling in advanced non-small cell lung cancer. Ther Adv Med Oncol. 2022 Jul 26;14:17588359221112696. doi: 10.1177/17588359221112696. PMID: 35923926; PMCID: PMC9340413. The economic value of liquid biopsy for genomic profiling in advanced non-small cell lung cancer - PubMed (nih.gov) (last visited Jan. 27, 2024).

in second-line treatment and palliative care costs. Over 5 years, total budget impact was $432,554 ($0.0072 per member per month).[21]

III. Effect of Proposed Changes:

The bill creates definitions, including the following:

- "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes molecular, histologic, radiographic, and physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.
- "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing performed at a participating in-network laboratory facility that the Centers for Medicare and Medicaid Services has either certified or granted a waiver under the federal Clinical Laboratory Improvement Amendments of 1988.
- "Clinical utility" means that the test result provides information used in the formulation of a treatment or in a monitoring strategy that impacts a patient's outcome and informs the clinical decision.
- "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

Medicaid Program (Section 1)

The bill amends s. 409.905, F.S., relating to mandatory Medicaid services, to require the Agency for Health Care Administration (Agency) to cover biomarker testing for diagnosis, treatment, management, and ongoing monitoring of a recipient's disease or condition to guide treatment decisions when such testing provides clinical utility to the recipient and is demonstrated by medical and specified medical and scientific evidence, including but not limited to, any of the following:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- Nationally recognized clinical practice guidelines.

[21] Yu TM, Morrison C, Gold EJ, Tradonsky A, Arnold RJG. Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non-Small Cell Lung Cancer. Value Health. 2018 Nov;21(11):1278-1285. doi: 10.1016/j.jval.2018.04.1372. Epub 2018 Jun 8. PMID: 30442274. https://pubmed.ncbi.nlm.nih.gov/30442274/ (last visited Jan. 28, 2024).

Medicaid managed care plans under contract with the Agency must provide biomarker testing at the same scope, duration, and frequency as the Medicaid program otherwise provides to enrollees.

The Agency is also required to outline a process for enrollees and providers to request an exception to the biomarker testing coverage policy and to post this process on the Agency's website. The biomarker testing services may not be construed to require coverage of biomarker testing for screening purposes.

Currently, Florida Medicaid fee for service Medicaid and SMMC cover biomarker testing under s. 409.905(7), F.S., relating to Mandatory Medicaid services, Independent Laboratory Services. Florida Medicaid reimburses eligible providers for biomarker testing services in accordance with Rule 59G-4.190, F.A.C., the Laboratory Services and Coverage Policy, and Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules. Further, covered services must be medically necessary as defined by Rule 59G-1.010, F.A.C. not duplicate another service, and meet the criteria in the service specific coverage policy. When determining coverage or if it is appropriate to add a code to a FFS Medicaid fee schedule, the Agency considers clinical and practice guidelines as well as costs and maintaining budget neutrality.

Insurers and HMOs (Sections 2 and 3)
The bill creates s. 627.64055, F.S., relating to individual health insurance policies and s. 641.31708, F.S., relating to HMO individual and group contracts, to require such health insurance policies and HMO contracts issued on or after January 1, 2025, to provide coverage for biomarker testing.

An insurer issuing individual health insurance policies or HMO contracts must cover biomarker testing for diagnosis, treatment, management, and ongoing monitoring of a insured's or subscriber's disease or condition to guide treatment decisions when such testing provides clinical utility to the recipient and is demonstrated by medical and specified medical and scientific evidence, including but not limited to, any of the following:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- Nationally recognized clinical practice guidelines.

Insurers and HMOs must also outline a process for insureds and subscribers and providers to request an exception to the biomarker testing coverage policy and to post this process on the insurer or HMO's website. These provisions may not be construed to require coverage of biomarker testing for screening purposes.

Effective Date (Section 4)

The bill has an effective date of July 1, 2024.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Indeterminate. The mandated coverage is anticipated to reduce the overall costs of care of an enrollee, insured, or subscriber as a result of the use of a more targeted, optimal treatment protocol.

The fiscal impact of the bill on health insurers and HMOs is indeterminate.

C. Government Sector Impact:

Florida's Medicaid Program[22]

The bill would limit the Agency's ability to determine coverage of biomarker testing using the current Agency's established process. The bill could have both a significant operational and fiscal impact on the Medicaid Program as it would require the Agency to cover all codes that meet the clinical criteria defined by the bill.

[22] Correspondence from Patrick Steele, Legislative Affairs Director, Agency for Health Care Administration (Feb. 1, 2023). On file with Senate Banking and Insurance Committee staff.

CS/HB 885 (companion to SB 964) mandates specific criteria by which biomarker testing must be evaluated for coverage by Florida Medicaid. Currently, the Agency does not define "specific nationally recognized clinical practice guidelines" that are referenced in CS/HB 885 and SB 964 in rule for determining coverage. Covered services must be medically necessary as defined by Rule 59G-1.010, F.A.C., not duplicate another service, and meet the criteria in the service specific coverage policy. When determining coverage or if it is appropriate to add a code to a FFS Medicaid fee schedule, the Agency considers clinical and practice guidelines as well as costs and maintaining budget neutrality.

Typically, the Agency does not cover every code designated by the American Medical Association for a covered service. For example, the Agency covers integumentary and wound care supplies under s. 409.906 F.S., Optional Medicaid services. There are a total of 87 skin substitute procedure codes listed in the AMA CPT codebook. Of these, Florida Medicaid covers a total of 26 CPT codes.

There are numerous biomarker tests that are Propriety Laboratory Analyses (PLA) Current Procedural Terminology (CPT) codes. A PLA code is a code set approved by the American Medical Association (AMA) CPT Editorial Panel. These codes are corresponding descriptors for labs or manufactures that want to identify their proprietary test more specifically. Florida Medicaid currently covers 46 non-PLA biomarker CPT codes under the Laboratory Services Fee Schedule that are listed on the CMS List for Billing and Coding: Biomarkers for Oncology. Florida Medicaid does not typically include PLA codes on FFS fee schedules when determining coverage based on the Agency's current coverage determination process.

Currently, managed care plans have the flexibility to cover services above and beyond the Agency's fee schedules and coverage policies, as well as reimburse providers mutually agreed upon rates. Plans may not be more restrictive in coverage than the Agency and promulgated rule, as detailed in their contract.

As currently written, the bill requires the Agency to cover every biomarker test when the medical and scientific evidence, as outlined in the bill, indicates clinical utility to the recipient. This requirement will have a significant fiscal impact to the Medicaid program which is indeterminate and on-going as the number of PLA and non-PLA codes that could meet this criteria is unknown. The impact will be ongoing as the bill will require the Agency to cover a biomarker test every time a new test meets the criteria outlined in the bill.

State Group Insurance

The fiscal impact of the mandated coverage on the State Group Insurance is indeterminate. It is unclear what particular biomarker tests are currently covered and the criteria that is used to determine coverage.

VI. Technical Deficiencies:

The bill establishes criteria for the coverage of biomarker testing under individual health insurance policies and HMO contracts. An insurer or HMO must cover biomarker testing for diagnosis, treatment, management, and ongoing monitoring of an insured's or subscribers's disease or condition to guide treatment decisions when such testing provides clinical utility to the recipient and is demonstrated by medical and scientific evidence, including but not limited to, any of the following:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- Nationally recognized clinical practice guidelines.

The testing must provide clinical utility to the recipient and must be demonstrated by medical and scientific evidence, *including but not limited* to the three bulleted items above. It is unclear what other medical and scientific evidence could be used, and who would determine the admissibility of it. The term, "nationally recognized clinical practice guidelines," is defined but the definition does not specify or designate existing guidelines. It is unclear whether this is being delegated to the Agency to determine.

VII. Related Issues:

The bill requires Medicaid, insurers, and HMOs to provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, and ongoing monitoring of a subscriber's disease or condition to guide treatment decisions when the testing provides clinical utility to the patient as demonstrated by medical and scientific evidence. However, the bill requires the Agency, insurers, and HMOs to establish a process for enrollees, insureds, and subscribers and prescribing practitioners to request an exception to coverage of biomarker testing. The bill provides that the mandated coverage may not be construed to require coverage of biomarker testing for screening purposes. It is unclear what type of exceptions to coverage would be covered since clinical utility and specified medical and scientific evidence must be used to determine coverage initially.

Health Insurance Mandate Study

Section 624.215, F.S, requires advocates of legislative proposals which would mandate health coverage by a health insurer or HMO must submit to the Agency for Health Care Administration and the legislative committees having jurisdiction a report which assesses the social and financial impacts of the proposed coverage. Guidelines for assessing the impact of a proposed mandated or mandatorily offered health coverage, to the extent that information is available, must include specified information. Advocates for the legislation provided the following responses to the information delineated in the statute.[23]

[23] Correspondence from J. Rees (Feb. 2, 2024). On file with Senate Banking and Insurance staff. Report includes a bibliography of sources used for the report.

(a) The extent to which the treatment or service generally used by a significant portion of the population.

Patients who are diagnosed with certain types of cancer and other diseases for which biomarkers are available can receive biomarker testing to help providers determine the most effective form of treatment. It helps save critical time in a cancer fight by eliminating the uncertainty of trial and error and providing a form of precision medicine that has become widely used and relied upon in cancer care. Unfortunately, not all Floridians are benefiting from the latest advancements, which can contribute to widening disparities in access to the most appropriate and effective treatments.

(b) The extent to which the insurance coverage generally available.

Most plans cover some biomarker testing for some patients. Generally speaking, large employer sponsored plans and Medicare tend to have better coverage of biomarker testing than smaller private plans and Medicaid as they already adhere to national guideline recommendations such as those provided by the National Comprehensive Cancer Network (NCCN).

(c) If the insurance coverage is not generally available, the extent to which the lack of coverage result in persons avoiding necessary health care treatment.

Biomarker testing (and precision medicine) can not only save lives and improve quality of life – but this type of testing can potentially reduce health care costs by identifying which treatments can be most effective for which individual patient. By avoiding treatments that will be ineffective or cause adverse side effects

(d) If the coverage is not generally available, to extent to which the lack of coverage result in unreasonable financial hardship.

A recent study by Milliman looking at the cost implications of similar legislation estimates that robust coverage of biomarker testing would result in premium impact of $0.14-$0.51 per member per month in the private market. This does not account for any potential cost savings from avoiding ineffective or unnecessary treatments. It does include additional profit insurers would build into the benefit costs. The average cost to insurers per biomarker test in the private market was $224.

(e) The level of public demand for the treatment or service.

Biomarker testing is not currently indicated for all cancer patients – However, requiring coverage for testing in line with medical and scientific evidence, like the clinical practice guidelines that oncologists rely on to determine when biomarker testing is appropriate has improved cancer outcomes and may lead to higher chances of survivorship against cancer. For example, patients with certain lung cancer types who received biomarker testing and targeted therapy had a 31 percent reduction in risk of death.

(f) The level of public demand for insurance coverage of the treatment or service.

There should be little doubt that patients would prefer to consume healthcare as a covered benefit as opposed to an out-of-pocket expense.

(g) The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.

There should be little doubt that patients would prefer to consume healthcare as a covered benefit as opposed to an out-of-pocket expense.

(h) The extent to which coverage will increase or decrease the cost of the treatment or service.

To the extent that coverage for clinically validated biomarker testing creates a path to ensure that more Floridians receive the right treatment at the right time, the overall cost of treatment would decrease. Without it, it is not uncommon for a patient to be put on several different therapies and undergo chemotherapy or immunotherapy without a clear indication that there is a likelihood of positive response.

There are several studies looking at the cost effectiveness of single marker testing, which are most likely to be covered by insurance plans currently, to more comprehensive testing, which isn't always covered. Comprehensive biomarker testing is often done with a panel test that assesses multiple biomarkers (e.g., genes or proteins) in one test as compared to single marker testing that assesses one marker per test. For many patients, panel testing is most appropriate. Examples include when there is limited tissue available for testing or as recommended by clinical practice guidelines to gain sufficient information to appropriately guide treatment decisions.

(i) The extent to which coverage will increase the appropriate uses of the treatment or service.

By aligning coverage for biomarker testing with the latest science, we can help increase access to precision medicine that can lead to better health outcomes and potentially reduce costs by allowing some Floridians to bypass costly and ineffective treatments and instead quickly identify which therapies will be most effective.

(j) The extent to which the mandated treatment or service will be a substitute for a more expensive treatment or service.

As discussed above, this testing can lead to better and faster therapy selection which can come with a significant cost savings as treatment is much more targeted.

For example, in a study sponsored by CVS Health looking at total cost of care for non-small cell lung cancer patients who received broad panel biomarker testing in comparison to narrow panel biomarker testing; broad panel testing had an average additional up-front cost increase of approximately $1,200 in comparison to narrow panel biomarker testing. However, those patients who underwent broad panel biomarker testing experienced a savings of approximately $8,500 per member per month in total cost of care, as a result of more optimal treatment

(k) The extent to which coverage will increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

The coverage criteria for biomarker tests are very clear and are determined as eligible only if they meet clear and robust medical and scientific evidence standards as defined in the bill, and only for the purposes spelled out in the bill. These sources of evidence are included to ensure that tests are covered if and only if they are demonstrated to be beneficial to patients and therefore the administrative expense would be minimal.

(l) The impact of this coverage on the total cost of health care.

Timely access to guideline-indicated comprehensive biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs. Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This testing can lead to treatments with fewer side effects, longer survival and allow patients to avoid treatments that are likely to be ineffective or unnecessary. Exposure to these ineffective treatments can exacerbate the physical, emotional, and economic burdens of disease. It is therefore likely that there could be a decrease in the total cost of care because of this more precise application of testing and therapy selection.

VIII. Statutes Affected:

This bill substantially amends section 409.905 of the Florida Statutes.
This bill creates sections 627.64055 and 641.31708 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.