Select Committee on Health Innovation

Monday, January 22, 2024
3:00 PM – 5:00 PM
Morris Hall (17 HOB)

Meeting Packet

Paul Renner
Speaker

Kaylee Tuck
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Select Committee on Health Innovation

Start Date and Time:	Monday, January 22, 2024 03:00 pm
End Date and Time:	Monday, January 22, 2024 05:00 pm
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 43 Medicaid Behavioral Health Provider Performance by Silvers
HB 885 Coverage for Biomarker Testing by Gonzalez Pittman
HB 1431 International Drug Reference Pricing by Fine, Massullo
HB 1639 Gender and Biological Sex by Bankson, Black

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m. Friday, January 19, 2024.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, January 19, 2024.

To submit an electronic appearance form, and for information about attending or testifying at a committee meeting, please see the "Visiting the House" tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 01/18/2024 4:08PM by Killings.Anola

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 43 Medicaid Behavioral Health Provider Performance
SPONSOR(S): Silvers and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation		Lloyd	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Florida has experienced a significant increase in psychiatric crisis hospitalizations of children and teens in recent years, and an increase in those children being repeatedly hospitalized in the same year. The Florida Medicaid program has a significant role in behavioral health care because it insures a disproportionate share of the children repeatedly hospitalized for behavioral health problems.

Medicaid managed care plans must meet standards set by the Agency for Health Care Administration (AHCA) for provider network adequacy; that is, for a sufficient number, type, and location of health care providers to meet the needs of a plan's enrollees. Current law requires AHCA to test managed care plan networks for network adequacy, but does not specify that AHCA must establish standards for all types of behavioral health providers. While current law requires AHCA to ensure access, current network testing methods do not adequately measure network sufficiency or ensure access to care.

HB 43 increases Medicaid managed care network adequacy and network testing requirements for behavioral health services.

The bill requires AHCA to establish network requirements for each type of behavioral health provider serving Medicaid enrollees, and improve its testing of behavioral health provider networks by including provider-specific data on access and appointment timelines.

The bill requires AHCA to establish specific, outcome-based, performance measures for Medicaid managed care plans to reduce high-utilization of crisis stabilization services by children and teenagers. The bill requires AHCA to include, at a minimum, plan-specific measures for year-over-year improvement.

Finally, the bill requires AHCA to report to the legislature annually, beginning October 1, 2024, on Medicaid-enrolled children who are high-utilizers of crisis stabilization services. The report must include demographic and geographic data, plan network testing data, and plan performance data based on the outcome performance measures established by AHCA under the bill. The report must also include an analysis of AHCA contract mechanisms for enforcing or incentivizing plan compliance with the requirements of the bill, and data on the use of those or other mechanisms by the agency, and any other actions taken by the agency to improve behavioral health outcomes for children in Medicaid.

The bill requires AHCA to amend managed care plan contracts by January 1, 2025, to reflect these changes.

The bill has an indeterminate, insignificant, negative fiscal impact on AHCA, and none on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

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 the Agency for Health Care Administration (AHCA) and financed by federal and state funds.

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

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.[4] Florida also has a waiver under Sections 1915(b) and (c) of the Social Security Act to operate the SMMC Long-Term Care (LTC) program.[5]

The Florida Medicaid program covers almost 5 million low-income individuals, including approximately 2.3 million children, or almost half of the children in Florida.[6]

Medicaid Behavioral Health Services

Medicaid provides coverage for behavioral health services, including both services in the community and inpatient hospitalization. Community services include crisis stabilization, transitional day services, therapeutic behavioral on-site services, psychosocial rehabilitation, medication and medication management, behavioral health overlay services, and community supports for independent living, among other services.

[1] Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725) (2016).
[2] S. 409.905, F.S.
[3] S. 409.906, F.S.
[4] S. 409.964, F.S.
[5] Id.
[6] Agency for Health Care Administration, *Medicaid Eligibles Report (December 31, 2023)* available at https://ahca.myflorida.com/medicaid/medicaid-finance-and-analytics/medicaid-data-analytics/medicaid-eligibles-reports (last viewed January 19, 2024).

For a child to obtain covered behavioral health services, a practitioner must formally assess the child's mental health status, substance use concerns, functional capacity, strengths, and service needs, to develop a plan of care.[7]

Federal law requires state Medicaid programs to provide all medically necessary services needed by a child, under the "Early and Periodic Screening, Diagnosis and Treatment" standard established by the federal Social Security Act.[8] This applies even to services not formally covered, and to services needed beyond the scope or duration of coverage.[9]

Behavioral Health Crisis Stabilization

Crisis Stabilization Units (CSUs) are specialized public receiving facilities that receive state funding to provide services to individuals showing acute mental health disorders. CSUs screen, assess, and admit for stabilization individuals who voluntarily present themselves to the unit, as well as individuals who are brought to the unit on an involuntary basis.[10] CSUs provide patients with 24-hour observation, medication prescribed by a physician or psychiatrist, and other appropriate services.[11]

The purpose of a crisis stabilization unit is to stabilize and redirect a client to the most appropriate and least restrictive community setting available, consistent with the client's needs.

Crisis stabilization services are covered by commercial health insurance, by Medicaid, and by the behavioral health safety net program for people without other coverage administered by the Department of Children and Families (Department)[12].

Child Baker Act Data

Recent years have seen a significant increase in the number of people requiring mental health crisis stabilization – particularly children and teenagers – as indicated by the table below. The table shows indicates the significant annual increase in involuntary examination of minors between 2001 and 2017, which rose from 14,997 in 2001 to 36,078 in 2017. The rate of child examinations also rose at a much higher rate than that in the general population: a 140% increase in that time period.

[7] Agency for Health Care Administration, Community Behavioral Health Services Coverage and Limitations Handbook, March 2014, p. 2-3.
[8] Title 42 U.S.C. 1396(d).
[9] See, e.g., Agency for Health Care Administration, Behavioral Health Therapy Services Coverage Policy, Nov. 2019, p. 3.
[10] S. 394.875(1)(a), F.S. Involuntary admissions are governed by the Florida "Baker Act". For involuntary patients the receiving facility must examine the patient within 72 hours of arrival. During that 72 hours, an involuntary patient must be examined by a physician or a clinical psychologist, or by a psychiatric nurse performing within the framework of an established protocol with a psychiatrist at a facility to determine if the criteria for involuntary services are met. If the patient is a minor, the examination must be initiated within 12 hours. By the end of that 72-hour examination period, one of the following must happen:

- The patient must be released;
- The patient must be released for voluntary outpatient treatment;
- The patient must consent to voluntary inpatient admission; or
- A petition for involuntary placement must be filed in circuit court for involuntary outpatient or inpatient treatment.

[11] Id.
[12] See, ch. 394 and ch. 397, F.S. DCF administers a statewide system of safety-net services for substance abuse and mental health (SAMH) prevention, treatment and recovery for children and adults who are otherwise unable to obtain these services. SAMH programs include a range of prevention, acute interventions (e.g. crisis stabilization), residential treatment, transitional housing, outpatient treatment, and recovery support services. Services are provided based upon state and federally-established priority populations.

Fiscal Year	All Ages			Minors (< 18)		
	Involuntary Exams	% Increase to FY17/18	Rate Per 100,000	Involuntary Exams	% Increase to FY17/18	Rate Per 100,000
2017-2018	205,781	N/A	1,005	36,078	N/A	1,186
2016-2017	199,944	2.92%	992	32,763	10.12%	1,092
2015-2016	194,354	5.88%	981	32,475	11.09%	1,097
2014-2015	187,999	9.46%	964	32,650	10.50%	1,102
2013-2014	177,006	16.26%	919	30,355	18.85%	1,030
2012-2013	163,850	25.59%	859	26,808	34.58%	914
2011-2012	154,655	33.06%	818	24,836	45.26%	848
2010-2011	145,290	41.63%	773	21,752	65.86%	743
2009-2010	141,284	45.65%	754	21,128	70.76%	702
2008-2009	133,644	53.98%	711	20,258	78.09%	664
2007-2008	127,983	60.79%	685	19,705	83.09%	643
2006-2007	120,082	71.37%	661	19,238	87.54%	652
2005-2006	118,722	73.33%	668	19,019	89.69%	651
2004-2005	114,700	79.41%	660	19,065	89.24%	664
2003-2004	107,705	91.06%	634	18,286	97.30%	648
2002-2003	103,079	99.63%	620	16,845	114.18%	606
2001-2002	95,574	115.31%	586	14,997	140.57%	547

2017 DCF Task Force

In 2017, the Legislature created a task force within DCF[13] to address the issue of involuntary examination of minors age 17 years or younger, specifically by:[14]

- Analyzing data on the initiation of involuntary examinations of minors;
- Researching the root causes of and trends in such involuntary examinations;
- Identifying and evaluating options for expediting the examination process; and
- Identifying recommendations for encouraging alternatives to or eliminating inappropriate initiations of such examinations.

The task force found that specific causes of increases in involuntary examinations of children are unknown. Possible factors cited in the task force report include an increase in mental health concerns, social stressors, and a lack of availability of mental health services.[15]

[13] Ch. 2017-151, Laws of Florida.
[14] Florida Department of Children and Families, *Task Force Report on Involuntary Examination of Minors,* (Nov. 2017), https://www.myflfamilies.com/service-programs/samh/publications/docs/S17-005766-TASK%20FORCE%20ON%20INVOLUNTARY%20EXAMINATION%20OF%20MINORS.pdf (last viewed January 19, 2024).
[15] Id.

As a follow up to the 2017 task force report, in 2019, the Legislature instructed DCF to prepare a report on the initiation of involuntary examinations of minors age 17 years and younger and submit it by November 1 of each odd numbered year.[16]

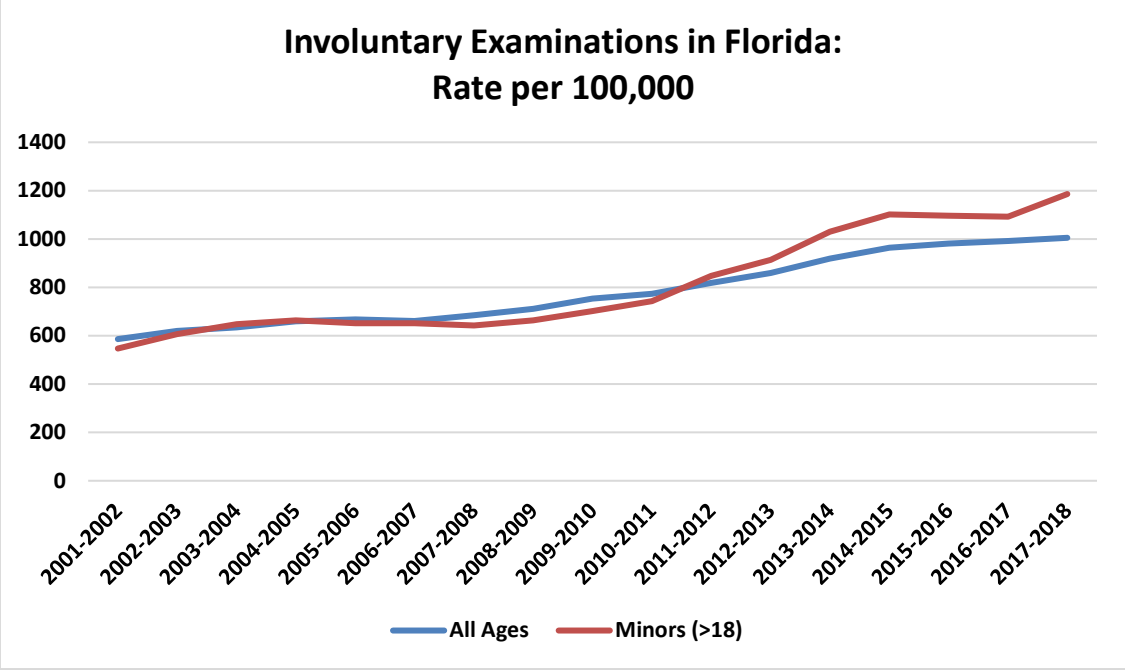
2019-2021 DCF Reporting

The 2019 report, revealed that some crisis stabilization units are not meeting the needs of children and adolescents with significant behavioral health needs, contributing to multiple exams.

The 2019 report found there were 205,781 involuntary examinations in FY 2017-2018, 36,078 of which were of minors.[17] From FY 2013-2014 to FY 2017-2018, statewide involuntary examinations increased 18.85% for children. Children had a larger increase in examinations compared to young adults ages 18-24 (14.04%) and adults (12.49%). Additionally, 22.61% of minors had multiple involuntary examinations in FY 2017-2018: up to 19 involuntary examinations in a single year. DCF identified 21 minors who had more than ten involuntary examinations in FY 2017-2018, with a combined total of 285 examinations. DCF's review of medical records found:

- Most initiations were a result of minors harming themselves and were predominately initiated by law enforcement (88%);
- Many minors were involved in the child welfare system and most experienced significant family dysfunction;
- Most experienced multiple traumas such as abuse, bullying, exposure to violence, parental incarceration, and parental substance abuse and mental health issues;
- Most had behavioral disorders of childhood, such as ADHD or Oppositional Defiant Disorder, followed by mood disorders, followed by anxiety disorders;
- Most involuntary examinations were initiated at home or at a behavioral health provider; and
- Discharge planning and care coordination by the receiving facilities was not adequate enough to meet the child's needs.

The 2019 report documented the significant increase in the rate of involuntary examinations of children, from a rate (per 100,000 population) of 547 in 2001 to a rate of 1,186 in 2018.



[16] Ch. 2019-134, Laws of Florida.
[17] Florida Department of Children and Families, *Report on Involuntary Examination of Minors, 2019,* (Nov. 2019), p. 25, https://www.usf.edu/cbcs/baker-act/documents/dcfoddyearreport2019.pdf (last visited January 19, 2024).

The 2021 report made similar findings, and updated the data.[18]

Table 1: Minors with Repeated Involuntary Exams				
# of Involuntary Exams	**Count of People**	**% of People**	**Count of Exams**	**% Exams**
1	18,378	76.03%	18,378	51.06%
2	3,393	14.04%	6,786	18.85%
3	1,143	4.73%	3,429	9.53%
4	498	2.06%	1,992	5.53%
5	271	1.12%	1,355	3.76%
6-10	409	1.69%	2,943	8.18%
11+	**79**	**0.33%**	**1,113**	**3.09%**
Counts of exams for children with 11 or more involuntary exams during the year are grouped together to redact for cell sizes lower than 10.				

The 2021 report noted that the vast majority of children with multiple crisis examinations in a year have Medicaid coverage, which should have provided greater access to community care that would help the children avoid the need for crisis care.[19]

Child Baker Act High Utilizer Project

Following up on this work, the Legislature in 2020 required DCF and AHCA to identify children and adolescents who are the highest users of crisis stabilization and inpatient psychiatric hospitalization services, collaboratively act to meet the behavioral health needs of those children, and submit a joint quarterly report during Fiscal Years 2020-2021 and 2021-2022 to the Legislature.[20] A "high utilizer" was defined by the Department and the Agency as children or adolescents under 18 years of age with three or more admissions into a crisis stabilization unit or an inpatient psychiatric hospital within 180 days.[21]

This reporting documented the fact that the vast majority of high utilizer children are covered by Medicaid, rather than by the Department safety net program, as indicated by the table below.[22]

Children Identified as High Utilizers Jan 2022 – Jun 2022		
SOURCE	COUNT	% of TOTAL
Medicaid	550	99%
DCF only (non-Medicaid)	7	1%
TOTAL	**557**	100%

[18] Florida Department of Children and Families, *Report on Involuntary Examination of Minors, November 2021,* Report on Involuntary Examination of Minors 2021.pdf (myflfamilies.com) (last viewed January 19, 2024).
[19] Id. at 11.
[20] S. 394.493(4), F.S.; Ch. 2020-107, L.O.F.
[21] Department of Children and Families and Agency for Health Care Administration, *Standards of Care in Facilities Providing Crisis Stabilization Services for Children and Adolescents, Findings and Recommendations (November 15, 2020)* available at Standards of Care in Facilities Providing Crisis Stabilization Services for Children and Adolescents (myflfamilies.com) (last viewed January 19, 2024).
[22] Department of Children and Families and Agency for Health Care Administration, Presentation to the House Subcommittee on Children, Families and Seniors, Feb. 8, 2023.

This reporting broke out the repeat child hospitalizations by Medicaid managed care plan, as indicated in the table below. Note that the plans highlighted in yellow are specialty plans, and have disproportionate numbers of children in their enrollment cohort with serious trauma (as with the Sunshine Child Welfare plan) or with serious mental illness (as with the Molina and Sunshine SMI plans). Higher rates of crisis treatment would be expected in those plans.[23]

Children < 19 Yrs. Identified as High Utilizers of CSU/ Inpatient Behavioral Health Services by Health Plan		
MMA Health Plan as of June 2022	Count of Children	High Utilizers Per 1,000 Enrollees
Aetna	2	0.02
Amerihealth	5	0.06
CCP	4	0.10
CMS Plan	49	0.57
FFS Provider	4	0.05
Humana	36	0.09
Molina	5	0.07
Molina - Serious Mental Illness*	15	3.42
Simply	34	0.08
Sunshine	142	0.14
Sunshine - Child Welfare*	129	3.33
Sunshine - Serious Mental Illness*	99	3.62
United	25	0.13
Vivida	1	0.06
Grand Total	550	0.21

AHCA reported on efforts made by the plans to improve care, including requiring managed care plans to assign the children a case manager and reaching out to parents to offer more services. According to AHCA, more than one-third of the parents contacted could not be reached or did not respond. In some instances, parents declined case management or specific service offer.[24] This may point to a need to address whole-family problems in order to assist the child.

Medicaid Provider Networks

Current law requires AHCA to establish network adequacy requirements for the managed care plans to meet when contracting with providers. Specifically, AHCA must establish standards for how many providers, the type of providers, and the regional distribution of providers are necessary for each plan to ensure access to care for the Medicaid recipients in their enrollment cohort. Each plan must establish a database of contracted providers and information about them, and publish the database online that allows Medicaid enrollees to compare provider availability to the network adequacy standards.[25]

Prior to 2020, Florida law did not expressly require the Medicaid program to test the provider networks, to confirm accuracy and compliance with the network standards.

Provider Network Testing

In 2020, the legislature required the Medicaid program to conduct (or contract for) systematic and continuous testing of the provider network databases to confirm accuracy. In addition, the legislature required more intensive network adequacy testing for the network of behavioral health providers.

[23] Id.
[24] Id.
[25] S. 490.967(2)(c)1., F.S.

Section 409.967(2)(c), F.S., requires AHCA to systematically and continuously test the behavioral health network to confirm:

1. That Medicaid behavioral health providers are accepting Medicaid patients; and
2. That Medicaid enrollees have access to behavioral health services.

AHCA implemented this requirement by conducting this testing in-house, as a desk review of the provider databases, or by requiring the plans to test themselves. In addition, AHCA performs periodic "secret shopper" testing by calling the provider offices and confirming[26]:

- Whether the provider's phone number and address listed in the database are correct;
- Whether the provider is available to see patients at the location listed;
- Whether the provider's staff is aware that the provider is in the plan's network; and
- Whether the provider is accepting new patients.

AHCA tests the network of behavioral health care *practitioners*; it does not test the network of inpatient or residential providers. AHCA does not establish network adequacy requirements for inpatient pediatric psychiatric beds or facilities, or assess the supply and demand for such services to determine whether there are access gaps.

This testing succeeds in identifying errors in the database and provider office confusion about participation in the plan. For example, one test of Humana practitioners in 2021 identified several providers with incorrect contact information, or which were no longer providing care at a listed location, or were no longer accepting Humana patients, or could not be reached at all.[27] A similar 2021 exercise across all plans for behavioral health practitioners identified several over 30 similar problems: provider not found, provider not at the listed location, provider does not accept new patients, and address and phone number problems.[28]

AHCA does not test how long it would take for a Medicaid enrollee to get an appointment with the practitioner, or use other methods of measuring the level of access to care. AHCA does not compile or publish reports on in its current testing results, or on trends.

Federal Network Adequacy Standards

Federal Medicaid rules require state Medicaid programs that use managed care models to develop specific quantitative standards for network adequacy, and monitor plan compliance with those standards. The federal Centers for Medicare and Medicaid Services (CMS) does not establish the specific standards for network adequacy; rather, it allows each state to develop its own guidelines and methods of measurement. However, the standards must ensure that beneficiaries have access to care,[29] and the plans must document to the state their ability to serve the anticipated enrollment before the contract begins and on an annual basis.[30]

The federal regulation does establish maximum wait times for routine appointments for primary care, obstetrics and gynecology, and outpatient mental health and substance use disorder care. Additionally, plan monitoring must include annual enrollee experience surveys for each Medicaid managed care plan, independent contractor calls to providers to verify access to appointments, and improvement plans when networks do not meet required levels.[31]

Effect of the Bill

[26] Agency for Health Care Administration, Agency Prescribed Secret Shopper Template, on file with staff of the House Subcommittee on Healthcare Regulation.
[27] Agency for Health Care Administration, Agency Prescribed Secret Shopper July 2021, on file with staff of the House Subcommittee on Healthcare Regulation.
[28] Agency for Health Care Administration, Agency Prescribed Secret Shopper, Q3 2021 Behavioral Health LDs, on file with staff of the House Subcommittee on Healthcare Regulation
[29] 42 CFR 438.68.
[30] 42 CFR 438.66.
[31] 42 CFR Part 438.

HB 43 increases Medicaid requirements for managed care plan provider network adequacy, related to behavioral health providers.

Medicaid Provider Networks

The bill requires AHCA to establish network requirements for each type of behavioral health provider serving Medicaid enrollees, and specifically include both community-based and residential providers. AHCA must amend current contracts by January 1, 2025, to reflect these changes.

In addition, the bill requires AHCA to improve testing of behavioral health provider networks by including provider-specific data on access timelines. The bill requires AHCA to contract to perform all network testing functions, rather than conduct testing in-house or rely on the managed care plans to test their provider directories, and provides that testing should be conducted on the actual network, not merely the provider database or directory.

Medicaid Behavioral Health Performance Measures

The bill requires AHCA to establish specific, outcome-based, performance measures for Medicaid managed care plans to reduce high-utilization of crisis stabilization services by children and adolescents. AHCA must, at a minimum, include plan-specific measures for year-over-year improvement.

AHCA must amend current managed care plan contracts by January 1, 2025, to reflect these changes.

Medicaid Performance Data

Finally, the bill requires AHCA to report to the legislature annually on Medicaid-enrolled children who are high-utilizers of crisis stabilization services. The report must include demographic and geographic data, and include plan performance data related to the outcome performance measures established by AHCA under the bill. In addition, the report must provide plan network testing data, including, at a minimum, an assessment of access timelines and data trends.

The report must also include an analysis of managed care plan contract mechanisms for enforcing or incentivizing compliance with the requirements of the bill, and data on the use of those or other mechanisms by the agency, and any other actions taken by the agency to improve behavioral health outcomes for children in Medicaid.

This extends and expands the high-utilizer reporting established by the legislature in 2020, which ended in 2022. The first annual report is due October 1, 2024.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 409.967, F.S, related to managed care plan accountability.
Section 2: Creates an unnumbered section of law, related to Medicaid contract amendments.
Section 3: Creates an unnumbered section of law, related to data reporting.
Section 4: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill requirement for AHCA to contract for network adequacy testing has an unknown, but insignificant, cost. Current contracted services allocations are sufficient to fund the requirements of the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Medicaid managed care plans may reallocate their Medicaid capitated payments or establish other initiatives to improve performance in behavioral health. Plans that improve performance will experience cost-avoidance savings due to fewer repeat hospitalizations of children.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not appear to affect county or municipal governments

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rule-making authority to implement the provisions of the bill

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to Medicaid behavioral health provider performance; amending s. 409.967, F.S.; revising provider network requirements for behavioral health providers in the Medicaid program; specifying network testing requirements; requiring the Agency for Health Care Administration to establish certain performance measures; requiring managed care plan contract amendments by a specified date; requiring the agency to submit an annual report to the Legislature; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (c) and (f) of subsection (2) of section 409.967, Florida Statutes, are amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) Access.—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and

children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider. The agency shall ~~conduct, or~~ contract for~~,~~ systematic and continuous testing of the plan provider networks ~~network databases maintained by each plan~~ to confirm accuracy, confirm that behavioral health providers are accepting enrollees, and confirm that enrollees have timely access to ~~behavioral health~~ services. The agency shall specifically and expressly establish network requirements for each type of behavioral health provider

serving Medicaid enrollees, including community-based and residential providers. Testing of the behavioral health network must also include provider-specific data on access timeliness.

2. Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

3. Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

4. Managed care plans serving children in the care and custody of the Department of Children and Families must maintain complete medical, dental, and behavioral health encounter information and participate in making such information available to the department or the applicable contracted community-based care lead agency for use in providing comprehensive and

coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department shall be the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

(f) Continuous improvement.—The agency shall establish specific performance standards and expected milestones or timelines for improving performance over the term of the contract.

1. Each managed care plan shall establish an internal health care quality improvement system, including enrollee satisfaction and disenrollment surveys. The quality improvement system must include incentives and disincentives for network providers.

2. Each managed care plan must collect and report the Healthcare Effectiveness Data and Information Set (HEDIS) measures, the federal Core Set of Children's Health Care Quality measures, and the federal Core Set of Adult Health Care Quality

Measures, as specified by the agency. Each plan must collect and report the Adult Core Set behavioral health measures beginning with data reports for the 2025 calendar year. Each plan must stratify reported measures by age, sex, race, ethnicity, primary language, and whether the enrollee received a Social Security Administration determination of disability for purposes of Supplemental Security Income beginning with data reports for the 2026 calendar year. A plan's performance on these measures must be published on the plan's website in a manner that allows recipients to reliably compare the performance of plans. The agency shall use the measures as a tool to monitor plan performance.

3. Each managed care plan must be accredited by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body, or have initiated the accreditation process, within 1 year after the contract is executed. For any plan not accredited within 18 months after executing the contract, the agency shall suspend automatic assignment under ss. 409.977 and 409.984.

4. The agency shall establish specific outcome performance measures to reduce the incidence of crisis stabilization services for children and adolescents who are high users of such services. Performance measures must at least establish plan-specific, year-over-year improvement targets to reduce repeated use.

Section 2. The Agency for Health Care Administration shall amend existing contracts with managed care plans to execute the requirements of this act. Such contract amendments must be effective before January 1, 2025.

Section 3. Beginning on October 1, 2024, and annually thereafter, the Agency for Health Care Administration shall submit to the Legislature an annual report on Medicaid-enrolled children and adolescents who are the highest users of crisis stabilization services. The report must include demographic and geographic information; plan-specific performance data based on the performance measures in s. 409.967(2)(f), Florida Statutes; plan-specific provider network testing data generated pursuant to s. 409.967(2)(c), Florida Statutes, including, but not limited to, an assessment of access timeliness; and trends on reported data points beginning from fiscal year 2021-2022. The report must include an analysis of relevant managed care plan contract terms and the contract enforcement mechanisms available to the agency to ensure compliance. The report must include data on enforcement or incentive actions taken by the agency to ensure compliance with network standards and progress in performance improvement, including, but not limited to, the use of the achieved savings rebate program as provided under s. 409.967, Florida Statutes. The report must include a listing of other actions taken by the agency to better serve such children and adolescents.

Section 4. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Select Committee on Health Innovation

Representative Silvers offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (a) of subsection (3) of section 409.966, Florida Statutes, is amended to read:

409.966 Eligible plans; selection.—

(3) QUALITY SELECTION CRITERIA.—

(a) The invitation to negotiate must specify the criteria and the relative weight of the criteria that will be used for determining the acceptability of the reply and guiding the selection of the organizations with which the agency negotiates. In addition to criteria established by the agency, the agency

shall consider the following factors in the selection of eligible plans:

1. Accreditation by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body.

2. Experience serving similar populations, including the organization's record in achieving specific quality standards with similar populations.

3. Availability and accessibility of primary care, behavioral health care, and specialty physicians in the provider network.

4. Establishment of community partnerships with providers that create opportunities for reinvestment in community-based services.

5. Organization commitment to quality improvement and documentation of achievements in specific quality improvement projects, including active involvement by organization leadership.

6. Provision of additional benefits, particularly dental care and disease management, and other initiatives that improve health outcomes.

7. Evidence that an eligible plan has obtained signed contracts or written agreements or has made substantial progress in establishing relationships with providers before the plan submits a response.

8. Comments submitted in writing by any enrolled Medicaid provider relating to a specifically identified plan participating in the procurement in the same region as the submitting provider.

9. Documentation of policies and procedures for preventing fraud and abuse.

10. The business relationship an eligible plan has with any other eligible plan that responds to the invitation to negotiate.

Section 2. Paragraphs (c), (d), (e), and (f) of subsection (2) and paragraphs (g), (h), (I), and (j) of subsection (3) of section 409.967, Florida Statutes, are amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) Access.—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be

sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2. By October 1, 2024, the agency shall specifically and expressly establish network standards for each type of behavioral health care provider, including, but not limited to, community-based residential providers. The standards shall ensure timely access to care and exceed any federal behavioral health network requirements. At a minimum, the agency shall, for each provider type, establish standards for:

a. Patient to provider ratios.

b. Maximum waiting times for appointments and admissions.

c. Availability of innovative health care service delivery methods, such as telehealth, mobile response services, and certified community behavioral health clinics.

3. The agency shall ~~conduct, or~~ contract with an independent vendor for~~,~~ systematic and continuous testing of the plan provider networks ~~databases maintained by each plan~~ to confirm accuracy, confirm that ~~behavioral health~~ providers are accepting enrollees, and confirm that enrollees have timely access to ~~behavioral health~~ services. Related to behavioral health providers, the vendor shall, at a minimum, test performance under the standards established by the agency under subparagraph 2. The vendor shall produce and the agency shall publish online quarterly and annual reports on plan network performance related to behavioral health, by plan and region, beginning April 1, 2025 and July 1, 2026, respectively.

4.~~2.~~ Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement

products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

5.~~3.~~ Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

6.~~4.~~ Managed care plans serving children in the care and custody of the Department of Children and Families must maintain complete medical, dental, and behavioral health encounter information and participate in making such information available to the department or the applicable contracted community-based care lead agency for use in providing comprehensive and coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department shall be the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

(d) Quality care.—Managed care plans shall provide, or contract for the provision of, care coordination to facilitate the appropriate delivery of behavioral health care services in the least restrictive setting with treatment and recovery capabilities that address the needs of the patient. Services shall be provided in a manner that integrates behavioral health services and primary care. Plans shall be required to achieve specific behavioral health outcome standards, established by the agency in consultation with the department.

(e) Encounter data.—The agency shall maintain and operate a Medicaid Encounter Data System to collect, process, store, and report on covered services provided to all Medicaid recipients enrolled in prepaid plans.

1. Each prepaid plan must comply with the agency's reporting requirements for the Medicaid Encounter Data System. Prepaid plans must submit encounter data electronically in a format that complies with the Health Insurance Portability and Accountability Act provisions for electronic claims and in accordance with deadlines established by the agency. Prepaid plans must certify that the data reported is accurate and complete.

2. The agency is responsible for validating the data submitted by the plans. The agency shall develop methods and protocols for ongoing analysis of the encounter data that adjusts for differences in characteristics of prepaid plan

enrollees to allow comparison of service utilization among plans and against expected levels of use. The analysis shall be used to identify possible cases of systemic underutilization or denials of claims and inappropriate service utilization such as higher-than-expected emergency department encounters. The analysis shall provide periodic feedback to the plans and enable the agency to establish corrective action plans when necessary. One of the focus areas for the analysis shall be the use of prescription drugs.

3. The agency shall make encounter data available to those plans accepting enrollees who are assigned to them from other plans leaving a region.

(f) Continuous improvement.—The agency shall establish specific performance standards and expected milestones or timelines for improving performance over the term of the contract.

1. Each managed care plan shall establish an internal health care quality improvement system, including enrollee satisfaction and disenrollment surveys. The quality improvement system must include incentives and disincentives for network providers.

2. Each managed care plan must collect and report the Healthcare Effectiveness Data and Information Set (HEDIS) measures, the federal Core Set of Children's Health Care Quality measures, and the federal Core Set of Adult Health Care Quality

Measures, as specified by the agency. Each plan must collect and report the Adult Core Set behavioral health measures beginning with data reports for the 2025 calendar year. Each plan must stratify reported measures by age, sex, race, ethnicity, primary language, and whether the enrollee received a Social Security Administration determination of disability for purposes of Supplemental Security Income beginning with data reports for the 2026 calendar year. A plan's performance on these measures must be published on the plan's website in a manner that allows recipients to reliably compare the performance of plans. The agency shall use the measures as a tool to monitor plan performance.

a. The agency shall identify each individual HEDIS score earned by each managed care plan during the first full contract year for each measure in the Core Set of Children's and Adult behavioral health measures, and establish those scores as baseline indicators for each plan. The agency shall notify each plan of their baseline for each HEDIS score annually. The agency, in consultation with each plan, shall establish regional clinical outcome performance goals for each contract year for each plan. In establishing the performance goals, the agency shall take into account the plan's HEDIS baseline, population, enrollment, patient mix and clinical risk, and other factors established by the agency.

b. The agency shall establish specific outcome performance goals to reduce the incidence of crisis stabilization services for children and adolescents who are high users of such services. Performance goals must at, at a minimum, establish plan-specific, year-over-year improvement targets to reduce repeated use and ensure better behavioral health outcomes for children and adolescents.

c. A managed care plan that does not meet the behavioral health agency performance goals established under this paragraph may be subject to quality improvement projects, automatic assignment suspension, and administrative and contractual sanctions as determined by the agency.

3. Each managed care plan must be accredited by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body, or have initiated the accreditation process, within 1 year after the contract is executed. For any plan not accredited within 18 months after executing the contract, the agency shall suspend automatic assignment under ss. 409.977 and 409.984.

(4) ~~(3)~~ ACHIEVED SAVINGS REBATE.—

(g) A plan that exceeds agency-defined quality measures in the reporting period may retain an additional 1 percent of revenue. For the purpose of this paragraph, the quality measures must include:

1. ~~p~~Plan performance in~~for~~ preventing or managing complex, chronic conditions that are associated with an elevated likelihood of requiring high-cost medical treatments.

2. Plan performance in behavioral health, including reduction in the incidence of crisis stabilization services for children and adolescents; improvement in follow-up visit rates after behavioral health related hospitalization for children and adolescents; and reduction in behavioral health related emergency room visits for children or adults.

(h) The following may not be included as allowable expenses in calculating income for determining the achieved savings rebate:

1. Payment of achieved savings rebates.

2. Any financial incentive payments made to the plan outside of the capitation rate.

3. Any financial disincentive payments levied by the state or federal government.

4. Expenses associated with any lobbying or political activities.

5. The cash value or equivalent cash value of bonuses of any type paid or awarded to the plan's executive staff, other than base salary.

6. Reserves and reserve accounts.

7. Administrative costs, including, but not limited to, reinsurance expenses, interest payments, depreciation expenses,

bad debt expenses, and outstanding claims expenses in excess of actuarially sound maximum amounts set by the agency.

The agency shall consider these and other factors in developing contracts that establish shared savings arrangements.

(i) Prepaid plans that incur a loss in the first contract year may apply the full amount of the loss as an offset to income in the second contract year.

(j) If, after an audit, the agency determines that a prepaid plan owes an additional rebate, the plan has 30 days after notification to make the payment. Upon failure to timely pay the rebate, the agency shall withhold future payments to the plan until the entire amount is recouped. If the agency determines that a prepaid plan has made an overpayment, the agency shall return the overpayment within 30 days.

Section 3. The Agency for Health Care Administration shall amend existing contracts with managed care plans to execute the requirements of this act. Such contract amendments must be effective before January 1, 2025.

Section 4. Beginning on October 1, 2024, and annually thereafter, the Agency for Health Care Administration shall submit to the Legislature an annual report on Medicaid-enrolled children and adolescents who are the highest users of crisis stabilization services. The report must include demographic and geographic information; plan-specific performance data based on

the performance measures in s. 409.967(2)(f), Florida Statutes; plan-specific provider network testing data generated pursuant to s. 409.967(2)(c), Florida Statutes, including, but not limited to, an assessment of access timeliness; and trends on reported data points beginning from fiscal year 2021-2022. The report must include an analysis of relevant managed care plan contract terms and the contract enforcement mechanisms available to the agency to ensure compliance. The report must include data on enforcement or incentive actions taken by the agency to ensure compliance with network standards and progress in performance improvement, including, but not limited to, the use of the achieved savings rebate program as provided under s. 409.967, Florida Statutes. The report must include a listing of other actions taken by the agency to better serve such children and adolescents.

Section 5. This act shall take effect July 1, 2024.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert:

An act relating to Medicaid behavioral health provider performance; amending s. 409.966, F.S.; revising quality selection criteria to specify inclusion of behavioral health care providers in the Medicaid program; amending s. 409.967, F.S.; revising provider network requirements for behavioral

health providers in the Medicaid program; specifying network testing requirements; requiring the Agency for Health Care Administration to establish certain performance measures related to behavioral health; requiring the agency to establish provider network standards; requiring managed care plan contract amendments by a specified date; requiring the agency to submit an annual report to the Legislature; providing an effective date.

HB 885

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 885 Coverage for Biomarker Testing
SPONSOR(S): Gonzalez Pittman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation		Lloyd	Calamas
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Biomarker testing is a method of looking for any structure, process, genes, proteins, and other substances in the body that can provide information that can be measured in the body or its products and influence or predict the incidence of outcome or 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 kinds of diseases. For cancer, for example, biomarker testing can help 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; and
- Whether the cancer treatment is working.

Different types of biomarker tests can be done to help determine the best cancer treatment options or what treatment options not helpful. Many tests look for gene changes in the cancer cells, while some measure certain proteins or other kinds of markers.

Biomarker testing for other diseases 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. Biomarker tests may be done on tumor samples removed during a biopsy or surgery, but some biomarker tests can be done on samples of blood or other bodily fluids.

Insurance coverage for biomarker tests varies. While many the large national health insurers cover it, such testing may be on a limited basis, may include prior authorization or prior approval processes, or may require higher out of pocket costs or copays. A 2019 study conducted of survivors by the Cancer Action Network of the American Cancer Society found that for most patients, the average out of pocket costs were less than $500 however, some covered patients did reports out of pocket costs in excess of $500.

HB 885 would require coverage for biomarker testing in Medicaid, individual, small, and large group health insurance plan policies, blanket and franchise group policies, and health maintenance organization policies beginning with new or renewing contracts on or after January 1, 2025. A recipient or insured and health care provider must have access to a clear and convenient process to request authorization for such testing through a readily accessible website of the insurer or plan. Coverage would not be required for biomarker testing for screening purposes.

The bill has an indeterminate, negative fiscal impact on state and local government. See Fiscal Analysis.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Biomarker Testing

Biomarker testing is a way 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 takes into account not just incidence and outcome of disease, but also the effects of treatments, interventions, and even unintended environmental exposure, such as to chemicals or nutrients. In their report on the validity of biomarkers in environment risk assessment, the WHO has stated that a 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]

Biomarker testing is not helpful for all kinds of diseases, but in the example of biomarker testing for cancer, such testing can help 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 biomarker testing.[6] Furthermore, certain patients are much less likely to receive biomarker testing than others. Patients who are older, black, and uninsured or on Medicaid, receive biomarker testing much less frequently than those that were younger, white, or not enrolled in Medicaid.[7] In another study, more than a quarter of patients who did not receive recommended biomarker testing reported that it was because insurance was not covering the test at all and/or they would have incurred high out-of-pocket costs.[8]

Different types of biomarker tests can be done to help determine the best cancer treatment options. Many tests look for gene changes in the cancer cells, while some measure certain proteins or other

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[1] National Cancer Institute, *Biomarker Testing for Cancer,* Biomarker Testing for Cancer Treatment - NCI (last visited January 20, 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 January 21, 2024).
[3] Id.
[4] American Cancer Society, *Biomarker Tests and Cancer Treatment,* available Biomarker Tests and Cancer Treatment | American Cancer Society (last visited January 20, 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 January 20, 2024).
[7] Kenneth L. Kehl, Christopher S. Lathan, Bruce E. Johnson, Deborah Schrag, Race, Poverty, and Initial Implementation of Precision Medicine for Lung Cancer, *JNCI J Natl Cancer Inst, 2019, Vol. 111*, available at https://doi.org/10.1093/jnci/djy202 (last visited January 21, 2024).
[8] 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 January 21, 2024).

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.[9]

Biomarker tests may be done on tumor samples removed during a biopsy or surgery, but some biomarker tests can be done on samples of blood or other bodily fluids without being as invasive.[10] For certain types of cancer, biomarker testing is done routinely to assist with treatment decisions. Some cancer treatments, such as targeted therapies and immunotherapies, may only work for individuals with certain type of cancers.[11] However, biomarker testing may not be appropriate or helpful in all such situations. 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.[12]

Biomarker testing is conducted using a sample of an individual's cancer cells where the cells are analyzed to identify the specific biomarkers. The lab's report on the specific biomarkers will also identify the treatments that may be helpful for the cancer or the cancer's strains identified. Some biomarker tests also require a testing of healthy cells for comparison of a person's healthy cells to his or her cancer cells for different mutations.[13]

One type of biomarker that can be identified is a driver mutation which is a change in the DNA of a cancer cell and can cause a cancer cell to overgrow or a normal cell to become a cancer cell. The other type of biomarker is an immunotherapy biomarker which 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.[14]

A number of types of biomarker tests for molecularly targeted therapies are in clinical use ranging from single-gene tests to guide the use of a single class of therapy to a suite of multiple, but separate, tests for single analytes to guide 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 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 grown 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] *Supra,* note *4.*
[10] Id.
[11] *Supra*, note 1.
[12] *Supra*, note 4.
[13] Id.
[14] Genentech, *Understanding Biomarkers,* available at Learn About Biomarkers And Biomarker Testing in Advanced Non-Small Cell Lung Cancer | MyCareRoadMap By Genentech (last visited January 20, 2024).
[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 January 20, 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 January 21, 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 https://doi.org/10.1016/j.annonc.2021.04.003 (last visited January 21, 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 a cancer does not have certain biomarkers can also save a patient from undergoing unnecessary treatment or treatment that has not been as successful in a particular diagnosis or 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 patients and their 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 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.

Costs of Biomarker Testing

The costs of biomarker testing vary based on the type of testing being conducted and the type of disease being tested. The average allowed unit cost to insurers per biomarker test ranges from $78.71 (Medicaid) to $224.40 (large group self-insured).[24]

One study published in November 2022 found that among those with biomarker tests, the median per-patient total payer lifetime costs of all biomarker testing were $394/$462 (lung/metastatic lung) and $148/$232 (thyroid/metastatic thyroid).[25] In this study, total lifetime biomarker costs for payers ranged from a median of $128 (consumer-driven health plans) to $477 (preferred provider organizations). Median lifetime patient out-of-pocket costs were $0.00 for both tumor types and all payer types except for consumer-driven health plans ($12 for thyroid and $10 for metastatic lung).[26]

Costs vary by type of testing. The FDA has provided marketing approval for the sale of direct to patient biomarker tests. One of these tests which was approved in 2019 can identify cancer-associated alterations in 324 genes in any type of solid tumor.[27]Different levels of screening tests can be ordered by a patient directly online or by a patient's health care provider for $299 - $350 for the cost of the test – not including the cost of analysis or review by the practitioner.[28]

For new cancer treatments, costs may be covered as part of clinical trials. If individuals participate in a clinical trial, costs of the testing are usual covered as part of participation.[29] Increasingly, clinical trials

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[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 January 20, 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 January 20, 2024).
[23] Id.
[24] 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, available at doi: 10.1016/j.jval.2018.04.1372, Epub 2018 Jun 8. PMID: 30442274. (last visited January 21, 2024).
[25] 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 visted January 21, 2024).
[26] Id.
[27] National Cancer Institute, *Genomic Profiling Tests Cleared by FDA Can Help Guide Cancer Treatment, Clinical Trial Enrollment (December 21, 2017) (last visited January 21, 2024).*

[29] Supra, note 4.

report the enrollment of individuals based on the specific genetic mutation or alteration and not which organ the cancer originated from.[30]

Coverage by Public and Private Insurers

Medicare

Medicare provides biomarker testing when conducted in accordance with its national and local coverage determination guidelines and specific coverage details.[31] Medicare includes clinical laboratory diagnostic tests that, for example, predict the risk associated with one or more genetic variations. The diagnostic laboratory tests can provide a report of test results of genetic variations which are essential for the safe and effective use of a corresponding therapeutic product. Medicare announced coverage of biomarker testing and Next Generation Sequencing (NGS), a technique that can also measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion with an in vitro diagnostic test in local and national determination coverage determination letters in 2000 in 2002.[32] Current billing codes and guidelines for each testing component are listed on the Medicare website and updated at least annually.[33, 34]

Medicaid

Florida Medicaid covers biomarker testing under s. 409.905(7), F.S., as a mandatory Medicaid service under independent laboratory services. Eligible providers are reimbursed for biomarker testing under Rule 59G-4.190, Florida Administrative Code (F.A.C.), the Laboratory Services and Coverages Policy and Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules. The services provided to the eligible recipient must be determined to be medically necessary, not duplicative of another service, and meet the criteria of the policy.

The Medicaid Laboratory Services Policy covers reimbursement for:

- Chemistry;
- Clinical cytogenetics;
- Diagnostic immunology;
- Genetic carrier screening;
- Hematology;
- Histocompatibility;
- Immunohematology;
- Microbiology; and
- Pathology.[35]

Medicaid managed care plans have the flexibility to cover services above and beyond Agency for Health Care Administration (AHCA) coverage policies, but they may not be more restrictive than AHCA policy.[36]

Private Insurance

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[30] 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 January 20, 2024).
[31] Centers for Medicare and Medicaid Services, Medicare Coverages Database, *Billing and Coding: Biomarkers for Oncology,* available at Article - Billing and Coding: Biomarkers for Oncology (A52986) (cms.gov) (last visited: January 20, 2024).
[32] Centers for Medicare and Medicaid Services, *National Coverage Determination – Next Generation Sequencing (NGS)(January 27, 2020),* available at NCD - Next Generation Sequencing (NGS) (90.2) (cms.gov) (last visited January 21, 2024)
[33] Centers for Medicare and Medicaid Services, *National Coverage Determination Tracking: Next Generation Sequencing (NGS),* available at NCD - Next Generation Sequencing (NGS) (90.2) (cms.gov) (last visited January 20, 2024).
[34] Centers for Medicare and Medicaid Services, *Local Coverage Determination, Genomic Sequence Analysis Panels in the Treatment of Solid Neoplasms (effective for services after April 2019)* available at LCD - Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810) (cms.gov) (last visited January 21, 2024).
[35] Rule 59G-4.190, F.A.C., *Laboratory Services and Coverage Policy,* available at 59G-4.190 Coverage Policy Proposed.pdf (last visited January 20, 2024).
[36] 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).

According to a 2022 analysis of biomarker testing coverage by Milliman, 48 states had no minimum coverage requirements for biomarker testing.[37] In 2020, Milliman reported that in the large group insurance market, 11 percent of biomarker testing claims were for multi-gene panel tests and that most patients received 2.4 biomarker tests. Ninety percent of the large groups in the Milliman study reported some coverage for biomarker testing and half of the self-insured large groups reported coverage for between 14.4 and 32.7 tests.[38]

One study projected the impact of legislation requiring robust coverage of biomarker testing, projecting an impact of $0.08-$0.51 per member per month. This does not account for any potential cost savings from avoiding ineffective treatments.[39]

For oncology biomarkers, the major national commercial payers generally cover the majority of biomarker testing when the clinical utility has been established as a component of FDA review; however, for other biomarkers that are not FDA-reviewed, commercial payers rely upon National Comprehensive Cancer Network (NCCN) guidelines, American Society of Clinical Oncology (ASCO) guidelines, Technology Assessment organizations, and peer-reviewed published evidence.[40] Often, evidence of clinical utility is the determinant of coverage.[41] The major national commercial payors may vary coverage when tests might be approved and the range of tests covered for certain cancers according to the 2020 review of commercial payors conducted by the National Cancer Action Network.

According to cancer advocates, even when a patient has insurance coverage for testing, the insured patient may encounter prior authorization or pre-approval processes before specific testing is approved, and the testing may incur increased cost sharing. One study commissioned by the American Cancer Action Network found more than 25 percent of patients declined testing because of the out of pocket costs required under their insurance plan.[42] This 2019 survey of cancer survivors found that 31 percent of those cancer survivors with coverage reported out of pocket costs of $500 or less and 15 percent reported out of pocket costs greater than $500.[43]

Regulation of Insurers and Health Maintenance Organizations

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk bearing entities.[44] The Agency for Health Care Administration (AHCA) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[45] As part of the certificate 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.[46]

All persons who transact insurance in this state must comply with the Code.[47] The OIR has the authority to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[48] and may investigate any matter relating to insurance.[49]

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[37] Gabriela Diguez and Jennifer Carioto, *The Landscape of Biomarker Testing in the United States (February 15, 2022),* Milliman, available at https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-us (last visited January 21, 2024).
[38] Id.
[39] Id.
[40] Gelareh Sadigh, MD, et al, *State legislative trends related to biomarker testing, Cancer (May 24, 2022)* available at State legislative trends related to biomarker testing - PubMed (nih.gov) (last visited January 20, 2024).
[41] American Cancer Society Action Network and LUNGevity Foundation, *Payer Coverage Policies of Tumor Biomarker Testing (September 2020),* available at ACS CAN and LUNGevity Payer Coverage Policies of Tumor Biomarker Testing.pdf (fightcancer.org) (last visited January 21, 2024).
[42] Cancer Action Network and American Cancer Society, *Survivor News: Biomarker Testing Survivor Findings Summary (September 28, 2020), available at* Survivor Views Biomarker Testing Polling Memo.pdf (fightcancer.org) (last visited January 21, 2024)
[43] Id.
[44] S. 20.121(3)(a), F.S.
[45] S. 641.21(1)(1), F.S.
[46] S. 641.495, F.S.
[47] S. 624.11, F.S.
[48] S. 624.307(4), F.S.

Mandated Insurance Coverage in Florida

A health insurance mandate is a legal requirement that an insurance policy or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Each mandate adds to the cost of a plan's premiums, depending on the cost of the service and projected utilization by enrolled patients.

Current Florida law requires every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurer, to submit to the Agency for Health Care Administration and the legislative committees having jurisdiction, a report that assesses the social and financial impacts of the proposed coverage.[50] To the extent information is available, the report should address:

- The extent to which the treatment or service is generally used by a significant portion of the population.
- The extent to which insurance coverage generally available.
- The extent to which insurance coverage is not generally available and results in persons avoiding necessary health care treatment.
- The extent to which lack of coverage result in unreasonable financial hardship.
- The level of public demand for the treatment or service.
- The level of public demand for insurance coverage of the treatment or service.
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.
- The extent to which coverage will increase or decrease the cost of the treatment or service.
- The extent to which coverage will increase the appropriate uses of the treatment or service.
- The extent to which the treatment or service will be a substitute for a more expensive treatment or service.
- The extent to which the coverage will increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.
- The impact of this coverage on the total cost of health care.

The House Health and Human Services Committee has not received a report for HB 885.

Insurance Coverage Mandates and the Patient Protection and Affordable Care Act

Essential Health Benefits

Under the federal Patient Protection and Affordable Care Act (PPACA),[51] all non-grandfathered health plans in the non-group and small-group private health insurance markets must offer a core package of health care services known as the essential health benefits (EHBs). While not specifying the benefits within the EHB, the PPACA provides 10 categories of benefits and services which must be covered and then required the Secretary of Health and Human Services to further define the EHB.[52] The 10 EHB categories include laboratory services.

The federal Patient Protection and Affordable Care Act (PPACA) requires each state to select its own reference benchmark plan as its EHB benchmark plan which all other health plans in the state use as a model.[53] Beginning in 2020, states could choose a new EHB plan using one of three options, including: selecting another's state benchmark plan; replacing one or more categories of EHB benefits; or

[49] S. 624.307(3), F.S.
[50] S. 624.215, F.S.
[51] Affordable Care Act, (March 23, 2010), P.L.111-141, as amended.
[52] 45 CFR 156.100. et seq.
[53] Patient Protection and Affordable Care Act, (March 23, 2010), P.L.111-141, as amended.

selecting a set of benefits that would become the state's EHB benchmark plan.[54] Florida selected its EHB plan before 2012 and has not modified that selection.[55]

If a state elects to amend its benchmark plan by imposing a statutory mandate to cover a new service, PPACA requires the state to pay for the additional costs of that mandate for the entire industry.[56] According to a recent study, only two states have chosen to enhance their EHB benchmark plans and have incurred the additional benefits penalty: Utah and Massachusetts.[57] Utah, for example, added a coverage mandate for applied behavioral analysis therapy for individuals with autism in 2014 and subsequently implemented a state rule to allow the state to reimburse the estimated five affected carriers for the autism claims with state funds.[58]

Annually, the federal Centers for Medicare and Medicaid Services issues a *Notice of Benefit and Payment Parameters (NBPP)* for the next plan year. The NBPP typically includes minor updates to coverage standards, clarifications to prior policy statements, and announcements relating to any major process changes. For the 2025 Plan Year which begins on January 1, 2025, the NBPP proposes to codify that any new, additional benefits included in a state's EHB plan would *not* be considered an addition to the state's EHB, and therefore not subject to the PPACA provision requiring the state to defray the cost for the industry.[59] This change is part of a proposed rule which has not yet been finalized, so it is unclear whether the PPACA state defrayal provision will apply in future.[60]

Prior to 2012, the Florida Office of Insurance Regulation (OIR) identified 18 state mandated benefits in its filings to the Centers for Medicare and Medicaid Services for purposes of establishing its benchmark plan under the PPACA.[61] Florida has not adopted any additional mandated benefits since 2012, so has not triggered the PPACA obligation to pay for the costs of newly-mandated benefits for the entire insurance industry.

Effects of the Bill

HB 885 imposes a coverage mandate for biomarker testing, and requires the state Medicaid program to cover biomarker testing.

Insurance Mandate

HB 885 creates ss. 627,64183, 627.66133, F.S., 641.31093, F.S., to require coverage of biomarker testing under the large and small group, health insurance policies or non-profit health service plans, group, blanket, or franchise, health insurance policies, and HMO policies issued under these statutory sections for new or renewing policies on or after January 1, 2025.

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[54] Centers for Medicare and Medicare Services, *Marketplace – Essential Health Benefits,* available at https://www.cms.gov/marketplace/resources/data/essential-health-benefits (last reviewed January 12, 2024).
[55] Centers for Medicare and Medicaid Services, *Information on Essential Health Benefits (EHB) Benchmark Plans,* Florida State Required Benefits, available at https://downloads.cms.gov/cciio/State%20Required%20Benefits_FL.pdf (last viewed on January 12, 2024).
[56] 42 U.S.C. section 1803 U.S. Preventive Services Task Force, *Skin Cancer Prevention: Behavioral Counseling (March 20, 2018)* available at Recommendation: Skin Cancer Prevention: Behavioral Counseling | United States Preventive Services Taskforce (uspreventiveservicestaskforce.org) (last reviewed January 12, 2024).
1(d)(3)(B) and implanted through 45 CFR 156.111.
[57] California Health Benefits Program, (CHBRP) (August 2023), *Issue Brief: Essential Health Benefits: Exceeding EHBs and the Defrayal Requirement,* p.2. available at *https://www.chbrp.org/sites/default/files/2023-08/EHB_Defrayal_FINAL.pdf* (last viewed January 13, 2024).
[58] Utah Admin. Code R590-283 – Notice of Proposed Rule (November 1, 2019), available at DAR File No. 44181 (Rule R590-283), 2019-22 Utah Bull. (11/15/2019)DAR File No. 44181 (Rule R590-283), 2019-22 Utah Bull. (11/15/2019) (last viewed January 13, 2024).
[59] CMS.GOV, *HHS Notice of Benefit and Payment Parameters for 2025 Proposed Rule (November 15, 2023),* available at https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2025-proposed-rule (last viewed January 12, 2024).
[60] Patient Protection and Affordable Care Act, *HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program, and Basic Health Program*, 88 Fed. Reg. 82510, 82553, 82630-82631, 82649, 82653-82654 (November 24, 2023)(to be codified at section 45 CFR 155.170 and 156.11).
[61] *Supra*, note 44.

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

Medicaid Coverage Requirement

HB 885 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. Under the till, 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;
- An NCD by federal CMS or a LCD made by the Medicare Administrative Contractor; 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 coverage provided to Medicaid recipients must be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. The bill requires that the recipient and recipient's ordering health care provider have access to a clear and convenient authorization process which is readily accessible on the website of the health insurer and nonprofit health service plan.

The bill requires Medicaid managed care plans provide coverage for biomarker testing in the same manner and scope as provided to other Medicaid recipients who are not enrolled in a managed care plan. The provision also requires that the recipient and his or her provider have easy access to a clear and convenient authorization process on the managed care plan's website.

HB 885 does not require Medicaid to provide biomarker testing for screening purposes. The bill further authorizes the agency to seek federal approval, if necessary to implement the coverage requirement.

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

B. SECTION DIRECTORY

Section 1: Amends s. 409.906, F.S.; optional Medicaid services.
Section 2: Creates s. 409.9745, F.S.; managed care plan biomarker testing.
Section 3: Creates s. 627.64183, F.S.; coverage for biomarker testing.
Section 4: Creates s. 627.66133, F.S.; coverage for biomarker testing.
Section 5: Creates s. 641. 31093, F.S.; coverage for biomarker testing.
Section 6: Providing an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill's mandated coverage requirements on all types of regulated health insurers in the state would impact the state employee group health plan. It is not known, however, if all or any of the state's contracted plans for state employees currently cover this benefit, at what benefit level or, if any, out of pocket costs apply to state employees. If not currently a covered benefit, its addition may require an increase in premiums to cover the increased cost, and thereby generate additional revenue to the State Employee Group Health Insurance Trust Fund (see Expenditures, below). No fiscal analysis has been received from the Department of Management Services for the State Employee Group Health Insurance program.

2. Expenditures:

Under current federal law (PPACA) and rule, Florida must defray the private sector costs to insurers and employers of the bill's biomarker testing benefit. The Milliman report projected the per member per month cost impact of between $0.20 and $0.31 for individual coverage, between $0.12 and $0.18 in the small group insurance market, and between $0.09 and 0.14 in the large group market based on the breadth of the coverage.[62] However, it is unclear the extent to which private insurers and HMOs do not currently cover biomarker testing; therefore, the potential fiscal impact to the state of defraying additional private sector costs is unknown.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

Local governments providing health insurance coverage for employees may need to raise premiums to cover the cost of the additional coverage required by the bill, which would generate additional revenue.

2. Expenditures:

While the additional coverage required by the bill would require local governments to pay for this coverage, the PPACA requirement for the state to defray such costs would negate the impact on local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private insurers and employers would experience cost increases to pay for biomarker testing, if not already covered under their plan. Insured patients may experience increased costs in the form of increased premiums or other forms of cost-sharing.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The county/municipality mandates provision of Art. VII, section 18, of the Florida Constitution may apply because this bill requires local governments to provide an additional health insurance coverage item. However, the cost of the additional coverage is unknown and many of the commercial plans which provide coverage to the municipalities and counties today may already include this benefit in their coverage to employees. In addition, counties and municipalities can expect to be made whole by the state for any increased expenditures under the bill, based on application of current federal law requiring states to defray the costs of additional health insurance coverage mandates.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The AHCA, OIR, and the DSGI have sufficient rule-making authority under current law to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

[62] Id.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to coverage for biomarker testing; amending s. 409.906, F.S.; authorizing the Agency for Health Care Administration to pay for biomarker testing under the Medicaid program for specified purposes, subject to specific appropriations; specifying circumstances under which such payments may be made; providing definitions; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; authorizing the agency to seek federal approval for biomarker testing payments; creating s. 409.9745, F.S.; requiring managed care plans under contract with the agency to provide services in the Medicaid program to provide coverage for biomarker testing for Medicaid recipients in a certain manner; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; creating ss. 627.64183, 627.66133, and 641.31093, F.S.; providing definitions; requiring certain individual health insurance policies; group, blanket, and franchise health insurance policies; and health maintenance contracts, respectively, to provide coverage for biomarker testing for certain purposes;

specifying circumstances under which such coverage may be provided; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (29) is added to section 409.906, Florida Statutes, to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or

chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(29) BIOMARKER TESTING SERVICES.—

(a) The agency may pay for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the recipient. Such medical and scientific evidence includes, but is not limited to:

1. A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

2. An indicated test for a drug approved by the United States Food and Drug Administration;

3. A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

4. A nationally recognized clinical practice guideline. As used in this subparagraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical

practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies 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.

(b) As used in this subsection, the term:

1. "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, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

2. "Biomarker testing" means an 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 is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA

Certificate of Waiver by the United States Food and Drug Administration for the tests.

3. "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(c) A recipient and participating provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this subsection. Such process shall be made readily accessible to all recipients and participating providers online.

(d) This subsection does not require coverage of biomarker testing for screening purposes.

(e) The agency may seek federal approval necessary to implement this subsection.

Section 2. Section 409.9745, Florida Statutes, is created to read:

409.9745 Managed care plan biomarker testing.—

(1) A managed care plan must provide coverage for biomarker testing for recipients, as authorized under s. 409.906, at the same scope, duration, and frequency as the Medicaid program provides for other medically necessary treatments.

(2) A recipient and health care provider shall have access to a clear and convenient process to request authorization for

biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the managed care plan.

(3) This section does not require coverage of biomarker testing for screening purposes.

Section 3. Section 627.64183, Florida Statutes, is created to read:

627.64183 Coverage for biomarker testing.—

(1) As used in this section, the term:

(a) "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, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA

Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A health insurance policy or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the insured. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized

clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies 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.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The insured and the insured's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health insurer and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 4. Section 627.66133, Florida Statutes, is created to read:

627.66133 Coverage for biomarker testing.—

(1) As used in this section, the term:

(a) "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, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A group, blanket, or franchise health insurance policy or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in

this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the insured. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies 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.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The insured and the insured's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health insurer and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 5. Section 641.31093, Florida Statutes, is created to read:

641.31093 Coverage for biomarker testing.—

(1) As used in this section, the term:

(a) "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, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A health maintenance contract or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the subscriber. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies 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.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The subscriber and the subscriber's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health maintenance

organization and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 6. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___ (Y/N)
ADOPTED AS AMENDED	___ (Y/N)
ADOPTED W/O OBJECTION	___ (Y/N)
FAILED TO ADOPT	___ (Y/N)
WITHDRAWN	___ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Select Committee on Health Innovation

Representative Gonzalez Pittman offered the following:

Amendment (with title amendment)

Remove lines 131-328 and insert:

Section 1. Subsection (5) is added to section 110.12303, Florida Statutes, to read:

110.12303 State group insurance program; additional benefits; price transparency program; reporting.—

(5) Coverage for biomarking testing.

(a) Effective for state group health insurance plan policies issued on or after January 1, 2025, the department shall provide coverage of biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a enrollee's disease or condition to guide

treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the enrollee. Such medical and scientific evidence includes, but is not limited to:

1. A labeled indication for a test approved or cleared by the United States Food and Drug Administration;

2. An indicated test for a drug approved by the United States Food and Drug Administration;

3. A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

4. A nationally recognized clinical practice guideline. As used in this subparagraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies 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.

(b) As used in this subsection, the term:

1. "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, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

2. "Biomarker testing" means an 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 is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA Certificate of Waiver by the United States Food and Drug Administration for the tests.

3. "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(c) Each contracted preferred provider organization and health maintenance organization shall provide a clear and convenient process for providers to request authorization for biomarker testing. Such process shall be made readily accessible to all enrollees and participating providers online.

(d) This subsection does not require coverage of biomarker testing for screening purposes.

T I T L E A M E N D M E N T

Remove lines 19-29 and insert:

biomarker testing; providing construction; amending s. 110.12303, F.S.; requiring the state employee health plan to provide coverage for biomarker testing for certain purposes; specifying circumstances under which such coverage may be provided; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; providing

HB 1431

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1431 International Drug Reference Pricing
SPONSOR(S): Fine and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1750

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation		DesRochers	Calamas
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2021, retail prescription drugs accounted for 8.9% of U.S. health spending. Over the last six decades, the United States recorded an exponential increase in prescription drug spending per capita, adjusted for inflation. Drug spending per capita increase from $101 in 1960 to $1,147 in 2021. Increased drug spending per capita is attributable in large part to the high cost of drugs in the United States.

The most recent comprehensive study comparing U.S. drug prices to similarly situated countries in the Organisation for Economic Co-operation and Development reveals that U.S. drug prices were in the aggregate 256% more than drug prices in other OECD countries. U.S. prices for brand-name originator drugs were 344% of prices in other OECD countries. High prescription drug costs contribute to poor medication adherence which leads to adverse downstream effects on health care spending and health outcomes.

International reference pricing refers to the practice of using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark, or reference price, that informs price setting or price negotiation of the product in the home jurisdiction. In other words, reference pricing sets an upper payment limit for purchasers. Reference pricing is a cost-containment policy strategy to ensure the maximum price paid for a drug is not excessive priced relative to its price in other countries.

HB 1431 requires the Agency for Health Care Administration (AHCA) to establish an upper payment limit for prescription drug coverage based on an international reference for each prescribed drug. The upper payment limit applies to Medicaid, the State Group Insurance Program, health maintenance organizations, authorized insurers offering health insurance, and a pharmacy's prescription drug transactions with cash-paying patients.

The bill creates a reporting requirement for drug manufacturers. Starting October 1, 2025, the bill requires drug manufacturers permitted by Department of Business and Professional Regulation to annually provide AHCA international prescription drug pricing data.

The bill requires the Office of Insurance Regulation and AHCA to submit a joint report every year detailing the impact of international drug reference pricing. The first annual report is due January 1, 2026.

The bill obligates health insurers to reduce beneficiary premiums and co-pays to reflect savings generated by applying the drug reference price to the reimbursement rate. The bill requires health insurers to document beneficiaries' anticipated savings and premium reductions in rate filings.

The bill has a significant negative fiscal impact on AHCA and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024. 5

FULL ANALYSIS

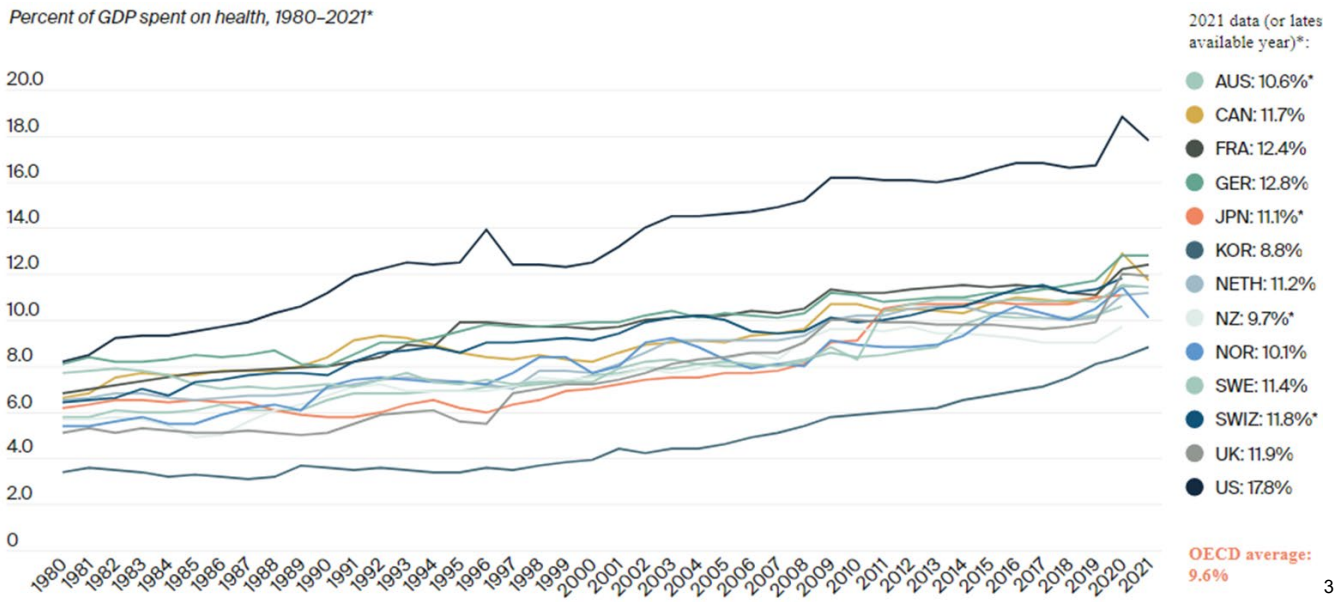
I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Spending in the United States

In 2021, the United States spent 17.8% of gross domestic product (GDP) on health care, nearly twice as much as the average country in the Organisation for Economic Co-operation and Development ("OECD")[1] which is 9.6%.[2]



[3]

Total health spending in the United States for 2021 reached $4.3 trillion.[4] Despite enormous health care spending, health outcomes in the United States are poor compared to other similarly situated countries in the international community.[5] Regrettably, the United States has the lowest life expectancy at birth, the highest death rates for avoidable or treatable conditions, the highest maternal and infant mortality, and among the highest suicide rates.[6]

The COVID-19 pandemic, recent broad-based inflation trends in the economy, and health sector employment trends complicate future spending projections.[7] However, as health care utilization returns to pre-pandemic levels, the average annual health care spending per person projection signals an

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[1] OECD. https://www.oecd.org/about/members-and-partners/ (last visited Dec. 11, 2023). The 38 OECD Member Countries are Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States.

[2] Munira Z. Gunja, Evan D. Gumas, Reginald D. William II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, The Commonwealth Fund (Jan. 31, 2023) https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 (last visited Dec. 5, 2023).

[3] OECD Health Statistics 2022 uses 2020 data. The chart reflects current expenditures on health for all functions by all providers for all financing schemes. Data points reflect share of GDP. OECD average reflects the average of 38 OECD member countries, including ones not shown here.

[4] Imani Telesford, Shameek Rakshit, Matthew McGough, Emma Wager, and Krutika Amin, *How has U.S. spending on healthcare changed over time?* Peterson-KFF Health System Tracker (Feb. 7, 2023) https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/ (last visited Dec. 8, 2023).

[5] *Id*.

[6] *Id*.

[7] Matthew McGough, Meghan Salaga, Cynthia Cox, and Krutika Amin, *How much is health spending expected to grow?* Peterson-KFF Health System Tracker (Oct. 11, 2023) https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow/ (last visited Dec. 5, 2023).

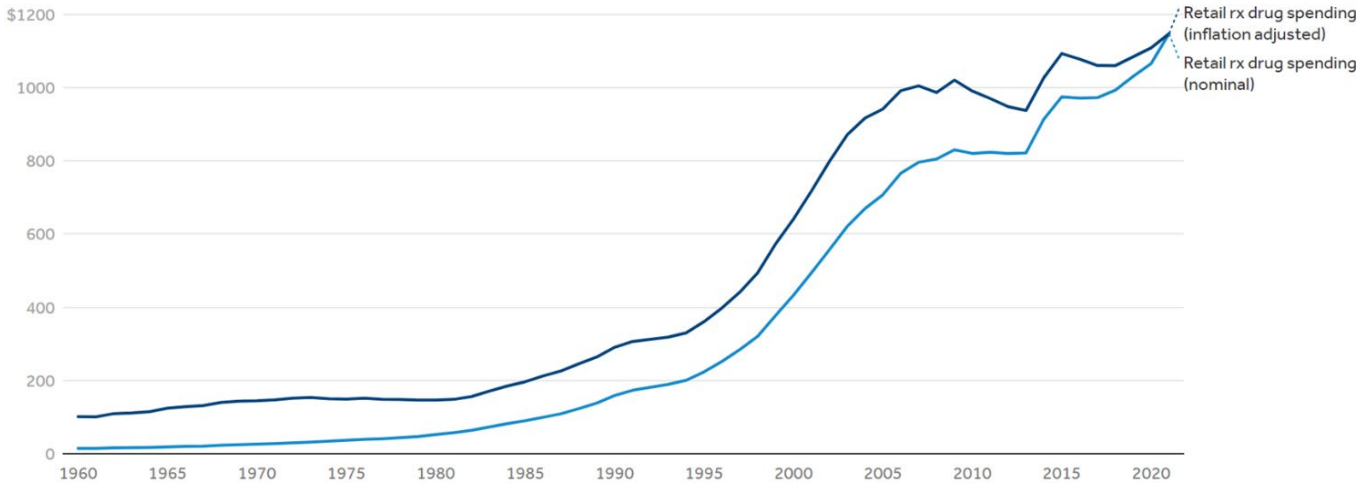
increase from 3.9% per capita during 2014 to 2019 to 4.8% per capita from 2022 to 2031.[8] Already, the average amount spent on health per person in the United states was $12,914 in 2021 – which dramatically exceeds both the OECD average ($6,125 per person) and the next closest OECD country, Germany ($7,383 per person).[9] For 2023 and beyond, health care spending may outpace overall economic growth and eventually hit 19.6% GDP by 2031.[10]

Pharmaceutical Spending

U.S. Pharmaceutical Spending

In 2021, retail prescription drugs accounted for 8.9% of U.S. health spending.[11] Over the last six decades, the United States recorded an exponential increase in prescription drug spending per capita, adjusted for inflation.[12] As the graph below indicates, prescription drug spending per capita increased from $101 in 1960 to $1,147 in 2021.[13]

Nominal and inflation-adjusted per capita spending on retail prescription drugs, 1960-2021



Some pinpoint the 1990s as the era when the relationship between high drug spending per capita and high drug prices manifested for the first time. Signature characteristics of the 1990s drug market include the rapid growth of brand-name drugs, increased advertising to physicians and consumers,[14] and the FDA's pivot to a user-fee model to expedite new drug approvals.[15] In addition, Medicare, Medicaid, and the Children's Health Insurance Program expanded coverage to prescription drugs.[16]

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[8] *Id*.
[9] Matthew McGough, Imani Telesford, Shameek Rakshit, Emma Wager, Krutika Amin, and Cynthia Cox, *How does health spending in the U.S. compare to other countries?* Peterson-KFF Health System Tracker (Feb. 9, 2023) https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/ (last visited Dec. 8, 2023).
[10] *Supra*, FN 7.
[11] Emma Wager, Imani Telesford, Cynthia Cox, and Krutika Amin, *What are the recent and forecasted trends in prescription drug spending?* Peterson-KFF Health System Tracker (Sept. 15, 2023) https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/ (last visited Dec. 5, 2023).
[12] *Supra*, FN 7.
[13] *Supra*, FN 11.
[14] Drug manufacturers advertise to encourage consumers to ask their doctors for specific medications. Aaron S. Kesselheim, *High Drug Prices in the US: What We Can Learn from Other Countries (and Some US States)*, Testimony to the United States Senate Committee on Health, Education, Labor, and Pensions (Mar. 23, 2021) https://www.help.senate.gov/imo/media/doc/Kesselheim1.pdf (last visited Jan. 15, 2024). Aaron Kesselheim is a Professor of Medicine at Harvard Medical School and the Director of Program on Regulation, Therapeutics, and Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Department of Medicine at Brigham and Women's Hospital.
[15] C. Michael White, *Why is the FDA Funded in Part by the Companies it Regulates?* UConn Today (May 21, 2021) https://today.uconn.edu/2021/05/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-2/ (last visited Jan. 15, 2024). C. Michael White is the Department Head & Distinguished Profession of Pharmacy Practice at the University of Connecticut School of Pharmacy.
[16] Austin Frakt, *Something Happened to U.S. Drug Costs in the 1990s*, The New York Times (Nov. 12, 2018) https://www.nytimes.com/2018/11/12/upshot/why-prescription-drug-spending-higher-in-the-us.html (last visited Jan. 15, 2024). Austin Frakt is a Senior Research Scientist in the Department of Health Policy and Management at Harvard T.H. Chan School of Public Health.

While a critical mass of prescription drug patents expired[17] throughout the mid-2000s, temporarily scaling back per capita spending, new biologic drugs directed a per capita spending resurgence in the mid-2010s. This era introduced precision medicine stemming from the completion of the human genome project. Precision medicine means drugs made for smaller populations to match specific genetic characteristics – making drugs more effective and creating a greater dependence on these drugs.[18]

Other factors contribute to high drug prices in the United States:

- Pharmaceutical market consolidation;[19]
- Until recently, Medicare did not negotiate drugs prices.[20]
- New medicine launches at record-high prices;[21]
- Increases in unit cost or dosage cost;[22]
- Delayed introduction of cheaper generic alternatives because drug manufacturers found ways to extend regulatory exclusivities;[23]
- Pharmacy benefit managers[24] and other intermediaries between drug manufacturers and consumers, [25]
- Lack of price transparency.[26]

U.S. Pharmaceutical Spending Compared to Other Countries

For all drugs, U.S. prices were 256% of prices in other OECD countries. U.S. prices for brand-name originator drugs were 344% of prices in other OECD countries. With the exception of unbranded generics, the magnitude of the difference between prices in the United States and those in other OECD countries was substantial. The bar graph below compares U.S. prices with OECD member countries. [27]

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[17] Patents endorse the drug manufacturer's sole right to sell and profit off their inventions and market exclusivities prevent generic and biosimilar competitors from entering the drug manufacturer's market for a period of time. Therefore, drug manufacturers producing drugs under patent or exclusivity protection have pricing power. Dicken, John, *Prescription Drug Spending*, The United States Government Accountability Office https://www.gao.gov/prescription-drug-spending (last visited Dec. 11, 2023).

[18] *Supra*, FN 15; Steven Schwartz, Millie Mo, Jinesh John, Ryan Chandanais, and Stephanie LaPointe*, Precision Medicine and the Pharmacist's Role as a Trusted Counselor in Specialty Pharmacy*, Pharmacy Times (May 19, 2020) https://www.pharmacytimes.com/view/precision-medicine-and-the-pharmacists-role-as-a-trusted-counselor-in-specialty-pharmacy (Jan. 15, 2024).

[19] *See* Robin Feldman, Brent D. Fulton, Jamie R. Godwin, Richard M. Scheffler, *Challenges with Defining Pharmaceutical Markets and Potential Remedies to Screen for Industry Consolidation*, 47 J. Health Pol. Pol'y & L. 583 (2022). https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2922&context=faculty_scholarship (last visited Jan. 15, 2024).

[20] Centers for Medicare & Medicaid Services, *Medicare Drug Price Negotiation*, U.S. Department of Health and Human Services (last updated Jan. 5, 2024) https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation (last visited Jan. 15, 2024); Evan D. Gumas, Paige Huffman, Irene Papanicolas, and Reginald D. Williams III, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*, The Commonwealth Fund (Jan. 4, 2024) https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally (last visited Jan. 15, 2024).

[21] Deena Beasley, *Focus: Newly launched U.S. drugs head toward record-high prices in 2022*, Reuters (Aug. 16, 2022) https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/ (last visited Dec. 11, 2023).

[22] American Academy of Actuaries, *Prescription Drug Spending in the U.S. Health Care System*, Issue Brief (Mar. 2018), available at: http://www.actuary.org/files/publications/PrescriptionDrugs.030718.pdf (last visited Dec. 11, 2023).

[23] *Id*. Delay tactics to extend the life of a brand-name patent include paying generic manufacturers to not enter the market, changing formulations, strengthening doses, and expanding FDA-approved uses for the brand-name drug.

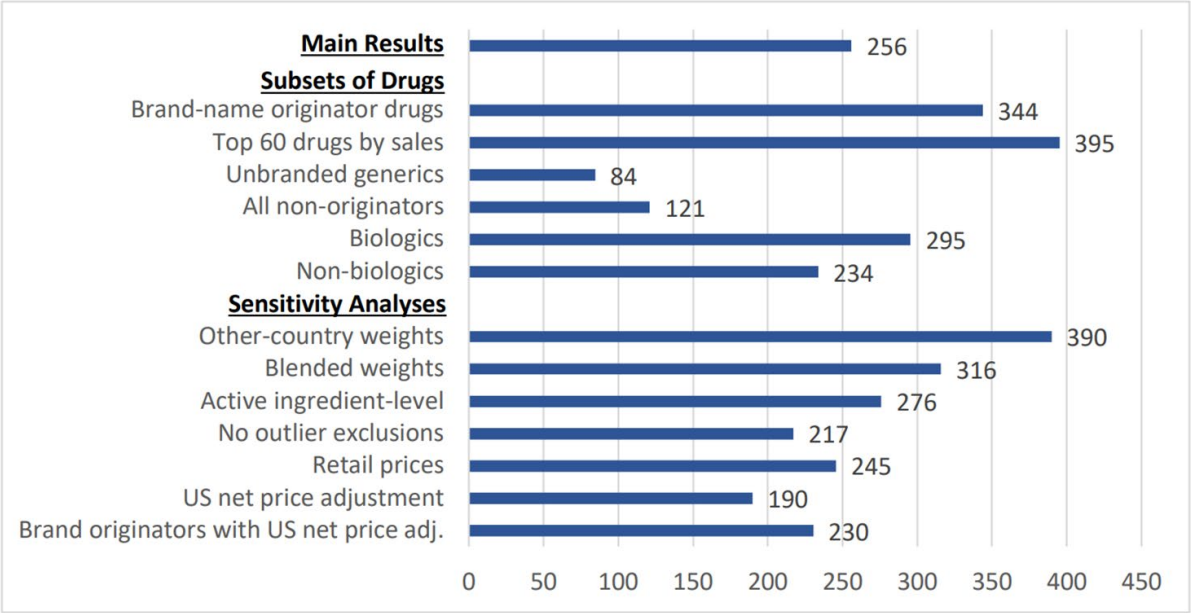
[24] The Commonwealth Fund, *Pharmacy Benefit Managers and Their Role in Drug Spending*, (April 22, 2019) available at https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf (last visited Aug. 14, 2023). Pharmacy benefit managers are intermediary companies that manage prescription drug benefits on behalf of pharmacy benefit plans or programs (health insurers, Medicare Part D drug plans, large employers, state health plans, and other payers).

[25] *Id*.

[26] *Id*.

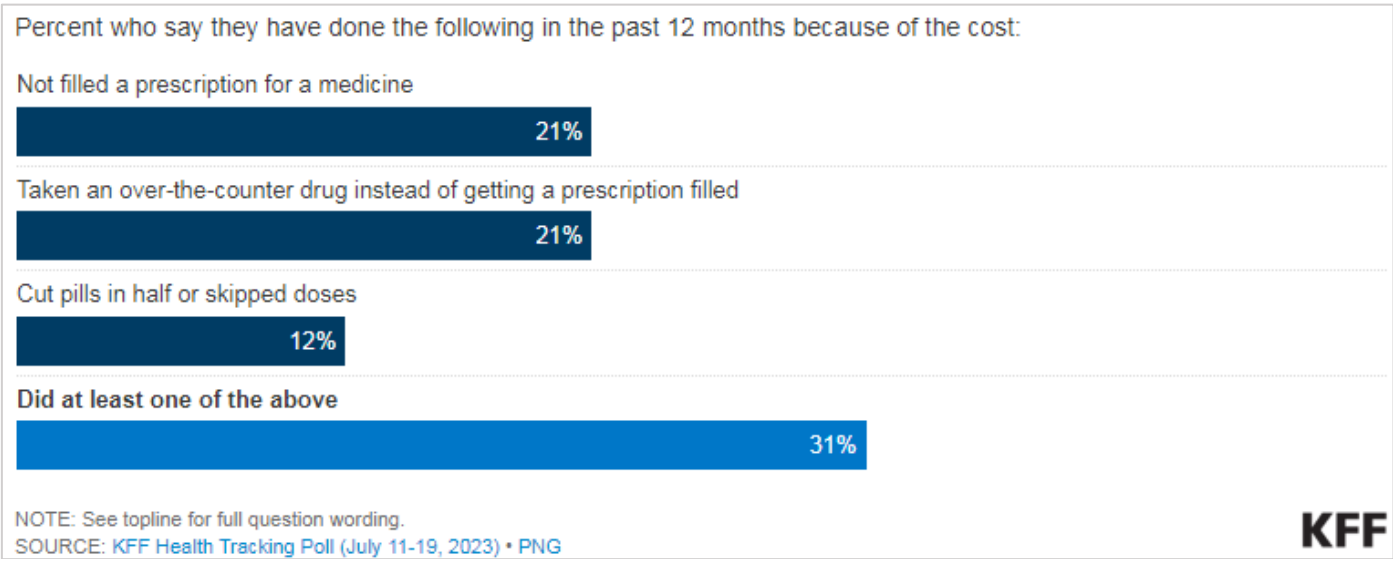
[27] Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, Alejandro U. Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corp. p. xiv (2021), https://www.rand.org/pubs/research_reports/RR2956.html (last visited Dec. 18, 2023). Authors analyzed IQVIA MIDAS

U.S. Drug Prices as a Percentage of Drug Prices in OECD Countries



Nonadherence

High prescription drug costs contribute to poor medication adherence which leads to adverse downstream effects on health care spending and health outcomes.[28] According to 2023 polling, six in ten adults say they currently take at least one prescription drug and a quarter say they currently take four or more prescription medications.[29] As shown by the graph below, about three in ten of the adults surveyed report not taking their medicines as prescribed at some point in the past year because of cost.[30]



sales and volume data for calendar year 2018. Comparison countries were the 32 OECD member countries at the time of the study. Authors compared the top 60 drugs by U.S. Sales at the active ingredient level.

[28] Julie Lauffenburger, Renee A. Barlev, Eniola Olatunji, Gregory Brill, and Niteesh Choudhry, *Costs of Prescription Drugs for Children and Parental Adherence to Long-Term Medications*, PubMed Central, National Library of Medicine (Oct. 6, 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10580109/ (last visited Dec. 7, 2023).

[29] Ashley Kirzinger, Alez Montero, Grace Sparks, Isabelle Valdes, and Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices: Methodology*, KFF, (Aug. 21, 2023) https://www.kff.org/report-section/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs-methodology/ (last visited Dec. 5, 2023). Methodology: July 11-19, 2023, online and telephone survey among a nationally representative sample of 1,327 U.S. adults. Margin of sampling error within the accepted ± 3 percentage points.

[30] *Id.*

The economic, clinical, and ethical consequences of medication non-adherence will continue to grow as the burden of chronic diseases intensifies.[31] Improving medication adherence provides an opportunity for major cost savings to healthcare systems.[32]

Pharmaceutical Regulation

The United States Food and Drug Administration

The United States Congress established the United States Food and Drug Administration (FDA) within the United States Department of Health and Human Services (HHS).[33] In part, FDA protects the public health by ensuring regulated drug products are safe and effective for human use.[34] Congress charges FDA to participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.[35]

Federal law classifies FDA regulated products as drugs,[36] biological products,[37,38] devices, or combination products.[39]

The FDA regulates the pharmaceutical distribution supply chain. The federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the introduction, delivery, and receipt of any drug in interstate commerce that is adulterated, misbranded, or unapproved by FDA.[40] The FD&C Act subjects the manufacturer, repackager, wholesale distributor, and dispenser to regulations according to their statutorily-defined roles in a transaction involving product.[41]

Patents

The United States Constitution gives Congress the power to enact laws relating to intellectual property.[42] Two forms of intellectual property (IP) rights incentivize the development of, and affect the pricing of, prescription drugs and biologics.[43] First, the United States Patent and Trademark Office may grant patents to drug manufacturers, which give the exclusive right to make and sell their novel pharmaceutical invention.[44] Second, for the term of the drug manufacturer's patent, the Food and Drug Administration (FDA) may grant regulatory exclusivities for innovative pharmaceuticals or

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[31] Rachelle Louise Cutler, Fernando Fernandez-Llimos, Michael Frommer, Charlie Benrimoj, and Victoria Garcia-Cardenas, *Economic impact of medication non-adherence by disease groups: a systematic review*, PubMed Central, National Library of Medicine (Jan. 21, 2018) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780689/ (last visited Dec. 7, 2023).
[32] *Id*.
[33] 21 U.S.C. § 393(a).
[34] 21 U.S.C. § 393(b)(2)(B).
[35] 21 U.S.C. § 393(3).
[36] The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines "drug" as articles recognized in the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans (or animals); articles (other than food) intended to affect the structure or any function of the human body (or animal body); and articles intended for use as a component in such articles. 21 U.S.C. § 321(g)(1).
[37] The Public Health Service Act (PHSA) defines "biological product" as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(i)(1).
[38] FDCA law applies to a biological product regulated by PHSA. 42 U.S.C. § 262(j).
[39] 21 U.S.C. § 360bbb-2(a).
[40] 21 U.S.C. § 331(a),(c); 21 U.S.C. § 355(a).
[41] 21 U.S.C. § 360eee(3), (10), (16), (29); 21 U.S.C. § 360eee-1(a)(1)-(2).
[42] "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Art I. § 8, cl. 8, U.S. Const.
[43] Jim Hahn, Kevin Hickey, Suzanne Kirchhoff, and Hannah-Alise Rogers, *Selected Issues in Pharmaceutical Drug Pricing*, Congressional Research Service (Mar. 1, 2023) https://crsreports.congress.gov/product/pdf/IF/IF12272 (last visited Dec. 20, 2023).
[44] *Id*. Patents are issued by the United States Patent and Trademark Office. A patent's term is generally 20 years.

pharmaceuticals serving particular needs.[45] Regulatory exclusivities mean the FDA will not approve applications for a generic or biosimilar form of the drug.[46]

The FD&C Act requires drug manufacturers to secure approval for their new drug before it can lawfully go to market.[47] When a drug manufacturer files a new drug application with the FDA, the FDA wants proof of the drug manufacturer's patent.[48] A drug manufacturer must list, as part of its NDA, any patent that claims the drug that is the subject of the application, or a method of using that drug.[49]

Once the drug manufacturer's patent term and regulatory exclusivities expire, other manufacturers may enter the market with generics or biosimilar products.[50] If the market functions properly, this new participation will bring down the formerly elevated price of the patented product to competitive levels.[51]

In 2007, the U.S. Court of Appeals for the Federal Circuit[52] acknowledged "[t]hese two objectives – to reward innovators with higher profits and to keep prices reasonable for consumers – are in dialectic tension."[53] The Court observed "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods."[54] At the same time, the Federal Circuit cautioned "state law must yield to congressional enactments if it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[55]

Florida Department of Business and Professional Regulation

The Florida Department of Business and Professional Regulation (DBPR)'s Division of Drugs, Devices, and Cosmetics regulates prescription drug manufacturers under the Florida Drug and Cosmetic Act.[56] The Florida Drug and Cosmetic Act safeguards the public health and promotes the public welfare by protecting the public from injury by product use and merchandising deceit involving drugs, devices, and cosmetics.[57] The Florida Drug and Cosmetic Act conforms with FDA drug laws and regulations.[58]

In Florida, DBPR regulates drug manufacturers, which are entities holding an FDA New Drug Application or Abbreviated New Drug Application for a drug or a Biologics License issued under the federal Public Health Service Act for a biologic.[59] Before operating in Florida, drug manufacturers must first obtain a permit issued by DBPR[60] and comply with statutory and regulatory requirements.[61] A prohibited act under the Florida Drug and Cosmetic Act includes the failure to obtain a permit or registration or operating without a valid permit.[62] DBPR rules classify the failure to obtain proper permitting as a level two Administrative Complaint with a fine ranging from $1,000 to $3,000 per

[45] Erin Ward, Kevin Hickey, and Kevin Richards, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, Congressional Research Service (Feb. 10, 2021) https://crsreports.congress.gov/product/pdf/R/R46679 (last visited Dec. 20., 2023)
[46] *Id*. Regulatory exclusivities vary in length from six months to 12 years, depending on the basis for exclusivity.
[47] 21 U.S.C. § 355(a).
[48] 21 U.S.C. § 355(b)(1).
[49] *Id*.
[50] *Biotechnology Industry Organization v. District of Columbia,* 496 F.3d 1369, 1373 (Fed. Cir. 2007).
[51] *Id*.
[52] The U.S. Court of Appeals for the Federal Circuit has exclusive jurisdiction over appeals of federal district court decisions relating to patents and appeals of decisions made by the Patent Trial and Appeal Board of the United States Patent and Trademark Office. 28 U.S.C § 1295(a)(1), (4).
[53] *Biotechnology Industry Organization*, 496 Fed. at 1373.
[54] *Id.* at 1372. The federal patent statute still does not expressly prohibit states from regulating the price of patented goods (current through Dec. 20, 2023).
[55] *Id*., citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).
[56] S. 499.05(1), F.S.
[57] S. 499.002(1)(a), F.S.
[58] S. 499.002(1)(b), F.S.
[59] S. 499.003(29), F.S. A drug manufacturer can also be the person who manufactured the drug or biologic if they lack an approved application or license, a co-licensed partner, or an affiliate.
[60] S. 499.01(1), F.S.
[61] Rule 61n-1.015, F.A.C.
[62] S. 499.005(22), F.S.

violation, and up to permanent suspension or revocation of permits.[63] A knowing failure to obtain a permit or registration or operating without a valid permit is a second degree felony.[64]

Prescription Drug Manufacturer Permit

Drugs manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[65] A prescription drug manufacturer who manufacturers or distributes prescription drugs in Florida must obtain a prescription drug manufacturer permit from DBPR. The permitted prescription drug manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[66] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[67]

Nonresident Prescription Drug Manufacturer Permit

A prescription drug manufacturer located outside of Florida who distributes prescription drugs in Florida must obtain a nonresident prescription drug manufacturer permit from DBPR.[68] The permitted manufacturer must comply with all of the same requirements as prescription drug manufacturers operating in Florida.[69] They must simultaneously comply with the licensing and permitting requirement of their home jurisdiction. If the nonresident manufacturer intends to distribute prescription drugs for which it is not the original manufacturer, an out-of-state prescription drug wholesale distributor permit is required. If a nonresident prescription drug manufacturer intends to import prescription drugs from a foreign county into Florida, they must provide DBPR a list identifying each prescription drug it intends to import. If a nonresident prescription drug manufacturer imports their product into Florida, they must also document FDA approval for importation.[70]

The table below reflects the number of active drug manufacturer permits issued by DBPR.[71]

Permit Type	Active Permits (as of Nov. 30, 2023)
Resident Prescription Drug Manufacturer	99
Nonresident Prescription Drug Manufacturer	755

Drug Manufacturer's Reportable Drug Price Increases

In 2023, Florida established a new reporting requirement for all prescription drug manufacturer and nonresident prescription drug manufacturer permitholders.[72] Specifically, permitholders must notify DBPR of a drug price increase on the date the increase becomes effective. [73] The reporting requirement applies to prescription drugs with a wholesale acquisition cost (WAC)[74] of at least $100 for a course of therapy before the effective date of an increase and to increases greater than 15 percent or more of WAC during the preceding 12 months or any cumulative increase of 30 percent or more of

[63] Rule 61n-1.024(5), F.A.C. DBPR has broad authority to deny, suspend, or revoke a permit or registration for a violation of state or federal law under s. 499.067, F.S.
[64] SS. 499.0051(3), 499.01(4)(g), F.S.
[65] S. 499.003(28), F.S.
[66] S. 499.01(2)(a), F.S.
[67] S. 499.003(16), F.S.
[68] S. 499.01(2)(c), F.S.
[69] *Id*.
[70] S. 499.01(2)(c), F.S.
[71] Email from Department of Business and Professional Regulation on file with the Florida House Health and Human Services Committee (Dec. 28, 2023).
[72] Ch. 23-29, Laws of Fla.
[73] S. 499.026(2), F.S
[74] "Wholesale acquisition cost" means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data. s. 499.026(1)(e), F.S.

WAC in the previous three calendar years. To calculate the 30 percent threshold, it must be based on the WAC in effect at the end of the 3-year period compared to the WAC at the beginning of the 3-year period.[75]

Since the law's effective date of July 1, 2023, DBPR has received price increase reports from several drug manufacturers.[76] By April 1 of each year, each drug manufacturer must submit an annual report to DBPR of all increases and cumulative increases on a DBPR form.[77] The first annual reports are due April 1, 2024.

Florida Agency for Health Care Administration

The Florida Agency for Health Care Administration (AHCA) is responsible for administering the Medicaid Program, licensing and regulating health facilities, and providing health care quality and price information to Floridians.[78]

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. AHCA administers the Florida Medicaid program, which is governed by both the federal and state governments and financed by both federal and state funds.

Florida uses a comprehensive managed care delivery model for primary and acute care services for the vast majority of Medicaid enrollees, the Statewide Medicaid Managed Care (SMMC) program.[79] The SMMC program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state. Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans.

Under federal Medicaid law, prescription drug coverage is an optional benefit states may choose to cover; Florida Medicaid covers prescription drugs.[80]

In addition to federally negotiated rebates, Florida Medicaid also negotiates for state-only manufacturer rebates, as known as state supplemental rebates. Current law specifies the threshold amount of supplemental rebates at 14% of the average manufacturer's price on the last day of the quarter. In addition, current law authorizes Florida Medicaid to require generic drug manufacturers to provide a minimum rebate of 15.1% of the average manufacturer price for the generic drug. There is no upper limit on the supplemental rebate amount.[81]

AHCA administers a prescription-drug spending-control program for Florida Medicaid which includes the use of a preferred drug list (PDL) and various utilization management techniques. The PDL is recommended by gubernatorially appointed Pharmaceutical and Therapeutics (P&T) Committee, which considers which drugs are medically appropriate, cost-effective therapeutic drugs for Medicaid enrollees. The P&T Committee also makes recommendations regarding the use of prior authorization.

[75] S. 499.026(1), F.S.
[76] Email from Department of Business and Professional Regulation on file with the Florida House Health and Human Services Committee (Dec. 28, 2023).
[77] S. 499.026(3), F.S.
[78] Office of Program Policy Analysis and Government Accountability, *Agency for Health Care Administration*, https://oppaga.fl.gov/ProgramSummary/ProgramDetail?programNumber=5048 (last visited Jan. 17, 2024).
[79] S. 409.964, F.S.
[80] S. 409.973(1)(x), F.S.
[81] S. 409.912(5)(a), F.S. AHCA may negotiate an amount lower than 14% of the average manufacturer price if the federal and/or supplemental rebate equal or exceeds 29%.

Current law requires the PDL to include at least two drugs in each therapeutic class, if feasible. AHCA requires prior authorization for Medicaid-covered prescription drugs not on the PDL.[82]

Medicaid managed care plans must follow the AHCA prescription drug coverage and utilization management requirements and use the preferred drug list, and may not establish their own preferred drug list. The plans establish the pharmacy networks, and may limit the size of pharmacy networks based on need, competitive bidding, price negotiations, credentialing, or similar criteria.[83]

Florida Canadian Prescription Drug Importation Program

The FD&C Act requires the HHS Secretary to regulate pharmacists and wholesalers who import prescription drugs from Canada into the United States.[84] With this regulatory power, HHS allows a state to sponsor a Section 804 Importation Program (SIP) [85] if the state regulates wholesale drug distribution and the practice of pharmacy and submits a proposal to FDA that describes a program to facilitate and supervise prescription drug imports from Canada.[86] FDA reviews SIP proposals and decides whether to approve or deny.[87]

Unless the FDA grants a state an exemption, SIP authorization to import prescription drugs from Canada automatically terminates after two years.[88] FDA may extend an authorization period for up to two years at a time.[89]

In 2019, Florida established the Canadian Prescription Drug Importation Program within AHCA to create a process by which certain state-funded entities may import safe and effective prescription drugs from eligible Canadian suppliers at lower cost to the state.[90] In November 2020, AHCA officially submitted its Section 804 Importation Proposal to FDA for Florida's Canadian Prescription Drug Importation Program.[91] Florida sued FDA in August 2022 because FDA had yet to render a decision on the proposal.[92]

In January 2024, FDA authorized Florida's Drug Importation Program for a two-year period – beginning on the date FDA receives notification that the first imported shipment of drugs. Before Florida imports prescription drugs from Canada, AHCA must fulfill three obligations:

1. Submit additional drug-specific information for the FDA's review and approval,
2. Ensure that the drugs Florida seeks to import have been test for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards, and
3. Relabel the drugs to be consistent with FDA-approved labeling.

In addition, AHCA must submit a quarterly report to the FDA that includes information about the imported drugs, costs savings, and any potential safety and quality issues.[93]

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[82] Ss. 409.912; 409.912(5)(a); 409.91195; 409.91196, F.S.
[83] *Id*.
[84] 21 U.S.C. § 804(b)
[85] Under the federal Food Drug & Cosmetic Act, the section 804 importation program (SIP) allows proposals from states or Native American tribes to import certain prescription drugs from Canada. FDA may authorize a SIP that will significantly reduce costs without imposing additional risk to public health and safety. U.S. Food & Drug Administration, *FDA News Release: FDA Authorizes Florida's Drug Importation Program*, U.S. Department of Health and Human Services (Jan. 5, 2024) https://www.fda.gov/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program (last visited Jan. 17, 2024).
[86] 21 C.F.R. § 251.2
[87] 21 C.F.R. § 251.4
[88] 21 C.F.R. § 251.6
[89] 21 C.F.R. § 251.8
[90] Ch. 19-99, Laws of Fla.
[91] The Executive Office of the Governor, *News Release: Governor Ron DeSantis Announces Florida's Submittal of Drug Importation Proposal to Federal Government*, State of Florida (Nov. 23, 2020) https://www.flgov.com/2020/11/23/governor-ron-desantis-announces-floridas-submittal-of-drug-importation-proposal-to-federal-government/ (last visited Jan. 17, 2024).
[92] Anthony Izaguirre, *Florida sues FDA over 'delay' of low-cost drug importations*, AP News (Aug. 31, 2022) https://apnews.com/article/health-lawsuits-florida-ron-desantis-57be1dbd66aae00b1912db8319352b01 (last visited Jan. 17, 2024).
[93] U.S. Food & Drug Administration, *FDA News Release: FDA Authorizes Florida's Drug Importation Program*, U.S. Department of Health and Human Services (Jan. 5, 2024) https://www.fda.gov/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program (last visited Jan. 17, 2024).

The Government of Canada issued a statement in response to the FDA's decision. According to Health Canada, Canada's Food and Drugs Act prohibits certain drugs intended for the Canadian market from being sold for consumption outside of Canada if that sale could cause, or worsen, a drug shortage in Canada. This includes all drugs that are eligible for bulk importation into the United States.[94]

AHCA is still in the process of implementing this program.

Trade Secret Information

Florida Uniform Trade Secrets Act

The Florida Uniform Trade Secrets Act (FUTSA) grants trade secret protection to information that derives independent economic value because that information is closely guarded to maintain its secrecy, not generally known, and not readily ascertainable to others who can obtain economic value from its disclosure or use. Protected information includes a proprietor's formula, pattern, compilation, program, device, method, technique, or process. [95]

When someone knowingly acquires a trade secret by improper means, or has reason to know that a trade secret was improperly acquired, they misappropriate the trade secret. A person can also commit trade secret misappropriation when they disclosure or use a proprietor's trade secret without the proprietor's express or implied consent.[96] A proprietor combats actual or threatened trade secret misappropriation with an action in court for injunctive relief and damages.[97]

Florida Public Records Requirements

Article I, s. 24(a) of the Florida Constitution sets forth the state's public policy regarding access to government records. This section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of art. I, s. 24(a) of the Florida Constitution.[98] The general law must state with specificity the public necessity justifying the exemption[99] and must be no broader than necessary to accomplish its purpose.[100]

Public policy regarding access to government records is addressed further in s. 119.07(1), F.S., which guarantees every person a right to inspect and copy any state, county, or municipal record, unless the record is exempt. Furthermore, the Open Government Sunset Review Act[101] provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. An identifiable public purpose is served if the exemption meets one of the following purposes:[102]

- Allow the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protect sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protect trade or business secrets.

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[94] Health Canada, *Statement from Health Canada on FDA decision on Florida bulk drug importation plan*, Government of Canada (Jan. 8, 2024) https://www.canada.ca/en/health-canada/news/2024/01/statement-from-health-canada-on-fda-decision-on-florida-bulk-drug-importation-plan.html (last visited Jan. 17, 2024).
[95] S. 688.002(4), F.S.
[96] S. 688.002(2), F.S.
[97] Ss. 688.003, 688.004, F.S.
[98] Article I, s. 24(c), Fla. Const.
[99] This portion of a public record exemption is commonly referred to as a "public necessity statement."
[100] Article I, s. 24.(c), FLA. CONST.
[101] Section 119.15, F.S.
[102] Section 119.15(6)(b), F.S.

Section 119.0715 specifically addresses trade secret information held by a state agency. Using the same definition of "trade secret" as found in chapter 688, this section makes trade secrets held by a state agency confidential and exempt from constitutional and statutory public records access requirements. Specifically, the information is exempt from public disclosure requirements, but since the information is also confidential, the agency is prohibited from sharing the information even if it chose to waive the exemption. State agencies are allowed to share trade secret information with other agencies, if within the scope of the other agency's official duties.

A state agency's contractor is also obligated to comply with constitutional and statutory public records requirements, including the requirement to maintain the confidentiality of records made confidential by law, such as trade secret material.[103]

Current law treats Medicaid program federal and state supplemental rebate amounts and percentages, and manufacturer prices, as confidential and exempt from the public disclosure requirements of the Florida Constitution and Ch. 119, F.S. This trade secret protection extends to the portions of AHCA's P&T Committee meetings during which supplemental rebate information is discussed.[104]

Health Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of health insurers and health maintenance organizations (HMOs) under the Florida Insurance Code (Code), Chapters 624, 627 and 641, F.S. The AHCA regulates the quality of care by HMOs under part III of ch. 641, F.S.

All persons who transact insurance in this state must comply with the Code.[105] The OIR has the authority to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[106] and may investigate any matter relating to insurance.[107]

Health Maintenance Organizations

A health maintenance organization (HMO) is any organization authorized under the Florida Insurance Code which:

- Provides, through arrangements with other persons, emergency care, inpatient hospital services, physician care, ambulatory diagnostic treatment, and preventative health care services.
- Provides, either directly or through arrangements with other persons, health care services to persons enrolled with such organization, on a prepaid per capita or prepaid aggregate fixed-sum basis.
- Provides, either directly or through arrangements with other persons, comprehensive health care services which subscribers are entitled to receive pursuant to a contract.
- Provides physician services, by physicians licensed under chs. 458, 459, 460, and 461, F.S., directly through physicians who are either employees or partners of such organization or under arrangements with a physician or any group of physicians.
- If offering services through a managed care system, has a system in which a primary physician licensed under chs. 458, 459, 460, or 461, F.S., is designated for each subscriber upon request of a subscriber requesting service by a physician licensed under any of those chapters and is responsible for coordinating the health care of the subscriber of the respectively requested service and for referring the subscriber to other providers of the same discipline when necessary.[108]

[103] Section 119.0701, F.S.
[104] S. 409.91196, F.S.
[105] S. 624.11, F.S.
[106] S. 624.307(4), F.S.
[107] S. 624.307(3), F.S.
[108] S. 641.19(12), F.S.

An HMO must apply for and obtain a certificate of authority to operate in Florida.[109] Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[110] As part of the certificate 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.[111] Once an HMO is issued a certificate, the HMO may enter into contracts in Florida to provide an agreed-upon set of comprehensive health care services, including drugs, to subscribers in exchange for a prepaid per capita sum or a prepaid aggregate fixed sum.[112]

Health Insurers

OIR reports that the individual health insurance market in Florida covers about two million people, and another 1.8 million receive coverage through the group health insurance market. Total premiums for the major medical market exceeded $23.5 billion in 2020 with approximately $12.5 billion in the individual market and $11.0 billion in the group market.[113]

The Florida Health Insurance Advisory Board (FHIAB) advises OIR, AHCA, the Department of Financial Services, other executive departments, and the Legislature on health insurance issues. As of year-end 2020, FHIAB reports that health insurance coverage by market segment consisted of:

- Individual Coverage – 1,962,686, an increase of 196,879 covered lives or 11.15%.
- Small Group (1-50 members) – 436,241, a decrease of 40,949 covered lives or 8.58%.
- Large Group (51+ members) – 1,408,647, a decrease of 83,036 covered lives or 5.57%.
- Total Market – 3,807,574, an increase of 72,894 covered lives or 1.95%.[114]

The declining trends in group enrollment have generally slowed down since the advent of the Affordable Care Act but were higher in 2020 possibly due to COVID-19 and its effects on employment. Other contributing factors may be that carriers have been active in developing products that help employers reduce costs by self-insuring. In addition, some small employers have chosen to stop offering coverage for their employees and their dependents as their employees can often pay less by purchasing a policy through the federal marketplace if those employees qualify for a subsidy.[115]

State Group Insurance Program

The State Group Insurance Program (SGI Program) is governed by ch. 110, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees, and includes health, life, dental, vision, disability, and other supplemental insurance benefits. The SGI program covers over 360,000 state employees, dependents, and retirees. The SGI Program typically makes benefits changes on a plan year basis, January 1 through December 31.

As part of the SGI Program, DMS is required to maintain the State Employee Prescription Drug Program (Prescription Drug Plan).[116] DMS contracts with Optum Rx, a pharmacy benefit manager, to administer the Prescription Drug Plan.[117]

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[109] S. 641.21(1), F.S.
[110] S. 641.21(1)(1), F.S.
[111] S. 641.495, F.S.
[112] Ss. 641.19(4), 641.31(1), F.S.
[113] *Supra*, FN 107.
[114] Florida Health Insurance Advisory Board, *2021 Florida Health Insurance Market Report*, Florida Office of Insurance Regulation (adopted Nov. 4, 2021) https://floir.com/docs-sf/default-source/life-and-health/health-insurance-advisory-board-reports/fhiab-2021-market-report---adopted-by-board-(11-4-21).pdf?sfvrsn=7da6c23c_4 (last visited Jan. 20, 2024).
[115] *Id*.
[116] S. 110.12315, F.S.
[117] Department of Management Services, *myFlorida, Prescription Drug Plan*, https://www.mybenefits.myflorida.com/health/prescription_drug_plan (last visited Jan. 20, 2024).

International Reference Pricing

International reference pricing (IRP), also known as external reference pricing, refers to the practice of using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark, or reference price, that informs price setting or price negotiation of the product in the home jurisdiction.[118] In other words, reference pricing sets an upper payment limit for purchasers.[119] Reference pricing is a cost-containment policy strategy to ensure the maximum price paid for a drug is not excessive relative to its price in other countries.[120]

While the technical aspects of reference pricing vary by country, the practice is widespread. Most countries in the European Union as well as Australia, Brazil, Canada, Egypt, Jordan, and South Africa use some form of reference pricing. [121]

In the United States, the best-known reference price index is the U.S. Department of Labor's Bureau of Statistics' Consumer Price Index (CPI). Generally, a price index like the CPI compares differences in prices for a basket of goods over time or across markets. The rationale behind price indices is that a comparison of prices is most meaningful when they isolate price variances by holding other variables like drug volume and mix constant. This approach is transferrable for price comparisons of prescription drugs amongst countries. [122]

International Reference Pricing Models

The precise impact of a reference pricing model depends on the variables chosen during the decision point phase.[123] Rather than serving as the primary negotiation tool, reference pricing tends to supplement other drug-pricing policies.[124] Generally, researchers anticipate substantial short-term savings in prices for established drugs because of the significant divide in prices between the United States and other high-income countries.[125] Savings appear greatest in nations where price revisions are frequent, the number of countries referenced is high, the lowest-price countries are weighted more heavily in calculations, and exchange-rate fluctuations are closely monitored.[126]

When short-term savings later declined in Italy and Sweden in the early 2000s, both countries scrapped their international reference pricing models.[127] In addition, researchers caution that manufacturers may pivot to preserve current prices in the United States by delaying drug launches in other countries, by exiting the lowest-price markets for established drugs, and by increasing drug launch prices in the United States.[128]

To thread the needle, some researchers believe a long-term, sustainable reference pricing policy that avoids price gaming and manipulation considers an alignment between drug prices and the value they bring.[129]

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[118] Dominic Voehler, Benjamin Koethe, Patricia Synnott, and Daniel Ollendorf, *The impact of external reference pricing on pharmaceutical costs and market dynamics*, p.1, Center for the Evaluation of Value and Risk in Health, Tufts Medical Center (Mar. 18, 2023) https://cevr.tuftsmedicalcenter.org/publications/the-impact-of-external-reference-pricing-on-pharmaceutical-costs-and-market-dynamics (last visited Dec. 12, 2023).
[119] Rachel Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, The National Academy for State Health Policy (Aug. 10, 2020) https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/ (last visited Dec. 12, 2023).
[120] *Supra*, FN 117 at 1.
[121] Daniel Ollendorf, Patricia Synott, and Peter Neumann, *External Reference Pricing: The Drug-Pricing Reform America Needs?* The Commonwealth Fund (May 27, 2021) https://www.commonwealthfund.org/publications/issue-briefs/2021/may/external-reference-pricing-drug-pricing-reform-america-needs (last visited Dec. 12, 2023).
[122] *Supra*, FN 27 at 3.
[123] Variables include the selection of target populations, the regulated transaction / point of sale, the drugs, the countries, the formula to calculate price, the frequency of price revisions, the granularity of prices and quantity, the data source(s), remedies for noncompliance, and ensuring benefits accrue to patients.
[124] *Supra*, FN 120.
[125] *Supra*, FN 117 at 7.
[126] *Supra*, FN 120.
[127] *Id*.
[128] *Supra*, FN 117 at 7.
[129] *Id*.

Medicare: Most Favored Nation Model

The federal Medicare program, administered by the Centers for Medicare and Medicaid Services (CMS), pays for covered health care services of qualified beneficiaries, including prescription drugs.[130] Medicare Part B covers physician care, outpatient services, and some home health and preventative services.[131] Medicare pays most health care practitioners for Part B outpatient prescription drugs and biologicals administered as part of, or incident to, a physician service, and drugs furnished for use with covered durable medical equipment.[132] Reimbursement for Part B covered drugs and biologicals is based on a statutory formula, which is the drug's average sales price plus a 6 percent add-on payment.[133]

The Most Favored Nation (MFN) model is a Medicare rate methodology recently published by CMS for prescription drugs, biologicals, and biosimilars in the Medicare Part B program. Under the MFN model, Medicare would pay no more than the lowest price paid in a similarly situated OECD member country.[134] The OECD countries comprise a set of countries that share with the U.S. both democratic principles and a commitment to market-based economies.[135]

The MFN model advanced initially as an interim rule in 2020 by CMS.[136] CMS's goal was to rein in unsustainable growth in Medicare Part B spending for the 50 single source drugs and biologicals that encompass a high percentage of Medicare Part B spending.[137] The interim rule did not address Medicare Part D drug spending.

The MFN model targets a specific point-of-sale transaction. When providers and suppliers who participate in the Medicare program submit a separately payable claim for a physician-administered drug on the MFN model drug list in the hospital out-patient setting, the price of that transaction serves as the reference price.[138]

CMS proposed benchmarking this reference price to the lowest per capita GDP-adjusted price of similarly situated OECD member countries (other than the U.S.). [139] To identify those countries, CMS developed an eligibility threshold of a least 60% of the U.S. Gross Domestic Product (GDP) per capita, updated quarterly.[140] For the first quarter of 2021, the CMS interim rule reported that the first basket group yielded 22 qualifying OECD member countries.[141]

The CMS interim rule anticipated significant savings using the MFN model over a 7-year period (2021-2027). The CMS Office of the Actuary reported savings in the amount of $64.4 billion in Medicare Fee-For-Service benefits, $49.6 billion in Medicare Advantage payments, $9.9 billion in Medicaid dual-

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[130] Kevin Hickey, Hannah-Alise Rogers, and Suzanne Kirchhoff, *Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Reponses and Potential Effects*, Congressional Research Service (Dec. 8, 2023) p. 1, https://crsreports.congress.gov/product/pdf/R/R47872 (last visited Dec. 20, 2023).
[131] *Id*.
[132] Centers for Medicare and Medicaid Services, *Part B Drugs and Biologicals*, U.S. Department of Health and Human Services (last updated Sept. 6, 2023) https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs (last visited Jan. 17, 2024).
[133] *Id*.
[134] Most Favored Nation (MFN) Model, 85 Fed. Reg. 76180 (Nov. 27, 2020).
[135] *Id*. at 76199.
[136] *Supra*, FN 133.
[137] *Id*. at 76180-76181
[138] *Id*. at 76181, 76187.
[139] This reference price methodology counteracts the current Medicare average sales price + 6% commission payments that tend to incentivize the procurement/prescription of drugs with higher ASPs.
[140] CMS chose the CIA World Factbook over the World Bank and the International Monetary Fund as its GDP per capita data source because the CIA World Factbook is a U.S.-issued report containing the most recent estimate of GDP per capita based on purchasing power parity for a country as well as historical data.
[141] These 22 qualifying OECD countries were Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

eligible beneficiary spending, and $28.5 billion for beneficiaries.[142] The HHS Office of the Assistant Secretary for Planning and Evaluation projected savings in the amount of $87.7 billion for the federal government, state governments, and beneficiaries.[143]

CMS never implemented the MFN model. A legal challenge to the interim rule on procedural grounds was successful, and the court enjoined the rule. CMS did not resolve the procedural problem and stopped the rule's advancement.[144]

National Academy for State Health Policy Model

The National Academy for State Health Policy (NASHP) state-based international referencing pricing model (NASHP Model) regulates the in-state purchase of drugs by setting the maximum price at which a payer is willing to provide reimbursement. This approach may enable a state to create upper payment limits on the basis of an international reference price while eschewing regulation that governs the price a manufacturer can charge for a product.[145]

The NASHP Model offers guidance on selecting the basket group of countries, the target drugs, enforcement remedies, and methods to share savings with beneficiaries:

- The basket group of countries should feature countries with comparable GDPs or similar economic conditions and countries with existing and accessible data sources containing price information.
- There are numerous options for selecting target drugs, including all drugs, the most costly drugs, the drugs of particular public salience, or the drugs whose prices exceed a specified amount for a particular time frame.
- Civil penalties could be enacted to enforce compliance, and noncompliance could also be deemed an unfair trade practice.
- The payers should pass along savings to beneficiaries through their premiums and copays.[146]

The NASHP Model anticipates a state's pursuit of a Medicaid waiver. The Social Security Act authorizes the HHS Secretary to waive Medicaid requirements when a state requests permission to conduct experimental, pilot, or demonstration projects, that in the judgment of the HHS Secretary, are likely to assist in promoting the objectives of the Medicaid program. A 1115 waiver could allow states to establish drug payments that vary from the federally-managed rebate system and any state supplemental rebate program. [147]

If the NASHP Model were applied to Medicaid, NASHP cautions states regarding the federal policy on the manufacturer's best price obligation: if one state's internationally benchmarked price is less than other states' Medicaid drug prices, the drug manufacturer must offer the internationally benchmarked price in every state where they do business with Medicaid. Under this policy, the federal rebate mechanism ensures Medicaid always gets the lowest price available for brand-name drugs. Generic drugs are not bound by the best price floor. To avoid triggering the manufacturer's best price obligation

[142] For modeling purposes, CMS used a federal government license to IQVIA's proprietary MIDAS data set. MIDAS data contains monthly estimates of drugs sales and volume from audits of drug transactions in different countries and distribution channels (e.g., retail pharmacies and hospitals).
[143] *Id*.
[144] CMS revoked their interim rule on December 29, 2021 following a nationwide preliminary injunction to enjoin enforcement of the MFN model in *California Life Sciences Association v. Center for Medicare and Medicaid*, 2020 WL 7690650 *1 (N.D. Cal. Dec. 28, 2020). ("The motion for a preliminary injunction is granted based on the government's failure to complete the notice and comment procedures by the Administrative Procedures Act"). Most Favored Nation (MFN) Model, 86 Fed. Reg. 73986 (Dec. 29, 2021).
[145] *Id*., *Supra*, FN 117.
[146] *Supra*, FN 117.
[147] *Id*.

in other states, the NASHP Model promotes a state supplement rebate agreement since state supplemental agreements are not subject to the best price floor. [148]

For commercial insurers and consumer retail purchasers, NASHP addresses the point-of-sale transaction by targeting the insurer's payment rate for drugs. The NASHP Model empowers a purchaser or payer to decline reimbursement for the drug in question that exceeds the maximum benchmarked price – whether the purchase is from the manufacturer or the wholesaler – even for physician-administered drugs. The state may obligate private purchasers and payers to participate on behalf of the state's residents. For a risk-averse approach, the NASHP Model recommends an ERISA[149] plan opt-in provision to avoid federal preemption issues.[150]

The acquisition of relevant international pricing information is necessary for a payer or regulator to set the benchmark price.[151] While the NASHP Model suggests any reporting and disclosure requirements could be legally and administratively costly, a state could alternatively purchase a license to a commercial database[152] that records international sales and volume or use publicly available data from other countries.[153] These sources probably use drug manufacturer gross prices for drugs because net prices (that is, the prices ultimately paid for drugs after negotiated rebates and other discounts are applied) are not publicly available in most markets.[154] However, gross pricing data is an inflated measure for reference pricing because the gross price is the manufacturer's list price before rebates and other negotiated discounts. To overcome this issue, some researchers take the additional step of adjusting prices downward based on an approximation of these discounts to account for these discounts.[155]

Furthermore, the NASHP Model cautions that some international pricing information is unavailable due to trade secret protections.[156]

Market-Based International Index Model

The Market-Based International Model (MBII) is a reference pricing model proposed by the Foundation for Research on Equal Opportunity (FREOPP). The MBII Model benchmarks reimbursement rates according to a weighted, two-tier formula focused on thirteen market-based health care systems.

- Tier 1: The Netherlands, Singapore, Switzerland, and Denmark. Drug prices are weighted at 60% of the overall MBII benchmark because these four countries are among the most market-oriented health care systems in the industrialized world.

- Tier 2: Austria, Belgium, the Czech Republic, France, Germany, Ireland, Japan, Portugal, and Slovakia. Drug prices are weighted at 40% of the overall MBII benchmark because these nine countries have a mix of private and public health insurance like the United States.

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[148] *Id*.; *See* 42 U.S.C. 1396r-8(b)(3)(A)(i)(II), (c)(1)(C)(i); Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019) https://www.kff.org/report-section/understanding-the-medicare-prescription-drug-rebate-issue-brief/#endnote_link_438418-9 (last visited Jan. 17, 2024).

[149] The Employee Retirement Income Security Act (ERISA) is a comprehensive economic plan of federal regulation governing private employee benefit plans. ERISA preempts state law with an impermissible connection to or an impermissible reference to ERISA regulated plans. Bryan Adkins, Alexander Pepper, and Jay Sykes, *Federal Preemption: A Legal Primer*, Congressional Research Service, pp. 7-8 (updated May 18, 2023) https://crsreports.congress.gov/product/pdf/R/R45825 (last visited Dec. 21, 2023).

[150] The NASHP Model acknowledges that the regulated transaction could alternatively be the manufacturer-pharmacy point-of-sale or the wholesale distributor-pharmacy point of sale.

[151] *Supra*, FN 118.

[152] RAND Corp. and the CMS Interim Rule utilized IQVIA's MIDAS commercial database. The Center for the Evaluation of Value and Risk in Health at Tufts Medical Center utilized EVERSANA's NAVLIN commercial database (formerly known as Pricentric ONE).

[153] E.g., the United Kingdom's National Health Service (NHS) Prescription Services produces the Drug Tariff on a monthly basis to show reimbursement amounts to pharmacy contractors. NHS Business Services Authority, *Drug Tariff*, https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff (last visited Jan. 17, 2024).

[154] *Supra*, FN 27.

[155] *Id*.

[156] *Supra*, FN 118. *See, also,* Steven M. Lieberman, Paul B. Ginsburg, and Kavita K. Patel, *Balancing Lower U.S. Prescription Drug Prices and Innovation – Part 1*, Health Affairs (Nov. 24, 2020) https://www.healthaffairs.org/content/forefront/balancing-lower-u-s-prescription-drug-prices-and-innovation-part-1 (last visited Jan. 20, 2024).

- Exclusions: Jurisdictions with government-run health care systems and drug price controls with little to no role for private insurance or market-based pricing.

If the benchmark price exceeds consumer inflation, the MBII caps the growth of prices at consumer inflation. The MBII Model authors suggest it accounts for costly, artificial market dynamics in the United States such as off-patent biologic drug pricing and biologic drugs regulatory exclusivities. The MBII Model acknowledges the necessity of standardized pricing data. In addition, the authors of MBII suggest further refinement by weighing the MBII benchmark by national prescription volume or equally weighing countries.

Effect of the Bill

International Reference Pricing Index

The bill creates a statutory framework for AHCA to build an international reference pricing index for prescription drugs for the commercial health insurance and Medicaid markets. The bill requires AHCA to contract with a vendor who will engineer, implement, and operate Florida's international reference pricing index. The bill details a three-pronged approach to building and maintaining the index: country-selection, drug pricing data acquisition, and the upper payment limit calculation.

Reference Price Source Countries

As to the first prong, the bill requires AHCA, through its contracted vendor, to designate a selection group of eligible countries that will comprise Florida's international reference pricing index. The bill deems eligible countries as follows:

- Countries with a real GDP per capita of at least 40% of US GDP per capita, and
- Countries without single-payer health systems (i.e., whole-market government price-setting for prescription drugs).

The real GDP per capita metric allows Florida to make a true assessment of purchasing power parity across all countries with the common denominator being the US GDP per capita, which is $63,700 according to the most recent estimate found in the U.S. Central Intelligence Agency's World Factbook. This means 40% of US GDP per capita is $25,480.

The table below identifies countries which currently meet the 40% GDP threshold and do not appear to rely exclusively on a single-payer health system.[157]

Country	Real GDP per capita	Real GDP per capita as a percentage of US GDP per capita ($63,700)
Austria	$54,100	84.9%
Belgium	$51,700	81.1%
Czech Republic	$40,700	63.8%
Denmark	$59,700	93.7%
Germany	$53,200	83.5%
Ireland	$102,500	160.9%

[157] U.S. Central Intelligence Agency's World Factbook, 2021.

Israel	$42,100	66.0%
Japan	$40,800	64.0%
Netherlands	$56,600	88.8%
Poland	$34,900	54.7%
Portugal	$33,700	52.9%
Romania	$30,800	48.4%
Singapore	$106,000	166.4%
Slovakia	$31,900	50.0%
Switzerland	$71,000	111.4%
The Bahamas	$30,200	47.4%

AHCA, through its contracted vendor, must reevaluate the selection group of countries annually. If a sourced country falls below the 40% threshold, those countries will be excluded for the next year. If a non-sourced country meets or exceeds the 40% threshold but operates a single payer health care system, that country will be excluded. If a non-sourced country meets or exceeds the 40% threshold and does not operate a single payer health care system, that country will be included for the next year.

The bill requires AHCA, through its contracted vendor, to tier the selection group of countries in two or more tiers, using an established index measuring the level of health care system market orientation in each country. A tiered listing of the selection group of countries is important to afford greater weight to prices derived from countries with pure market-driven health care systems.

Drug Pricing Data Acquisition

To obtain international and U.S. pricing data for the purpose of establishing reference prices, the bill creates a price reporting requirement for drug manufacturers. Starting October 1, 2025, drug manufacturers with a DBPR-issued prescription drug manufacturer, or nonresident manufacturer, permit must provide AHCA annual reports of international prescription drug pricing data.

Specifically, the bill requires the annual report to record the amounts for prescription drug paid by insurers, government benefit programs, and persons without health insurance in the countries included in the AHCA-established list of price source countries. The drug manufacturer may present these amounts in one of two modes:

- actual outpatient payment or reimbursement amounts, both net of rebates and other forms of discounts, or
- average payment amounts, weighted by utilization volume, if fully documented to AHCA.

Manufacturers may provide supplemental pricing data at any time throughout the year based on a change in the price of a prescription drug in one of the source countries.

The bill requires DBPR to enforce a permitted drug manufacturer's compliance with these new reporting requirements. DBPR must fine a noncompliant drug manufacturer $10,000 per day for the first 30 days. After the first 30 days, the bill requires DBPR to suspend a drug manufacturer's permit if the drug manufacturer remains out-of-compliance with the new reporting requirement.

Upper Payment Limit Calculation

The bill requires upper payment limits for each prescription drug to ensure patients and third-party payers in Florida will not a pay a higher price for the same prescription drug sold for less in international markets. To accomplish this purpose, the bill requires AHCA, through a contracted vendor, to compare

the source countries' prescription drug pricing data reported by drug manufacturers using publicly available, reliable, and consistent exchange rate source. The exchange rate source could be a commercial vendor or a government entity.

The bill establishes the following three-step process to calculate upper payment limits for each prescription drug.

1. The bill directs the comparative analysis of pricing data to yield the lowest price for each prescription drug across the selection group of countries selected for Florida's international reference pricing index.
2. AHCA, through its contracted vendor, adjusts the lowest price figure for each prescription drug by accounting for a country's variation in volume and GDP.
3. Finally, AHCA, through its contracted vendor, weighs the adjusted lowest price on a tiered-scale that measures the level of health care system market orientation in each country.

The upper payment limit calculation gives Florida the ability to derive the lowest price for each prescription drug sold across the international markets sourced by Florida's international reference pricing index.

AHCA's contracted vendor must reevaluate reference prices annually. In addition, the contracted vendor may reevaluate and update a specific reference price at any time based on a significant change in price documented by supplemental pricing data supplied by a drug manufacturer. The contracted vendor must send AHCA updated reference prices by January 1st of every year. Then, within 10 days of receipt, AHCA must publish references prices online.

Third party payers and pharmacies serving cash-paying patients will reference these internationally benchmarked lowest prices to determine the maximum amount that they will pay to cover each prescription drug. Ultimately, the upper payment calculation leverages purchasing power on the demand side of the supply chain as well as the prices that other countries are willing to pay for the same prescription drugs.

Insurer and Pharmacy Rate Regulation

The bill applies the upper payment limit to third party payers, including Medicaid, the State Group Insurance Program, and commercial health insurers and HMOs. The bill prohibits these payers from paying an amount more than the upper payment limit in any drug reimbursement transaction. These entities must refer to a prescription drug's reference price on Florida's international reference pricing index at the point-of-sale.

The bill requires covered health insurers to pass on the savings generated by international drug reference pricing to their policyholders. Specifically, the bill requires covered health insurers to use the savings to cut their policyholders cost sharing and premiums. As an accountability measure, the bill requires covered health insurers to document anticipated savings and premium reductions in their rate filings – beginning with the first-rate filing following the availability of reference prices.

The bill requires covered health insurers to assess the actuarial effect of Florida's international drug reference pricing program for each prescription drug the insurer covers for each plan year. By April 1st of every year, the bill requires covered health insurers to submit a report on the assessed effect to OIR Regulation or AHCA.

The bill also makes the reference price upper payment limit applicable to retail pharmacy transactions not involving third party payers: a pharmacy cannot charge a cash-paying patient an amount that exceeds the international reference price for that prescription drug.

The bill's upper payment limit does not apply to the pharmacy's dispensing fee, or fees to administer the prescribed drug; these practitioner fees would be accounted for separately, according to the contract with the payer.

Implementation Reporting

The bill requires OIR and AHCA to submit a joint report every year to the Governor, the President of the Senate, and the Speaker of the House of Representatives that details the following:

- The impact of the covered health insurers experience with Florida's international drug reference pricing program.
- The savings realized compared to prescription drug pricing in the United States without applying Florida's international drug reference pricing program.
- Any problems encountered.
- Any barriers to access prescription drugs.
- The domestic and foreign prescription drug market response.
- The impact on prescription drug program or beneficiary plan access to prescription drugs.
- Quality of care.
- Program costs.

This annual reporting requirement begins with the first annual report due January 1, 2026.

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

B. SECTION DIRECTORY:

Section 1: Creating s. 499.044, F.S., relating to international drug reference pricing.
Section 2: Amending s. 465.0244, F.S., relating to information disclosure and reference pricing.
Section 3: Amending s. 627.6044, F.S., relating to use of a specific methodology for payment of claims.
Section 4: Amending s. 641.30, F.S., relating to construction and relationship to other laws.
Section 5: Creating an unnumbered section of law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   AHCA anticipates spending $1,500,000 to implement the international drug reference pricing program. In addition, AHCA anticipates the need for $250,000 in recurring funds for program maintenance and enhancement and one FTE with a compensation package of $80,327.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

Local governments providing prescription drug coverage for employees will experience financial savings.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

HMOs and health insurers, and their employer and individual policy holders, will experience savings due to reductions in drug costs and commensurate reductions in premiums and other forms of cost-sharing.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides AHCA, DBPR, and OIR with sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to international drug reference pricing; creating s. 499.044, F.S.; providing legislative policy; requiring permitholders for prescription drug manufacturer permitholders to annually report certain international price data to the Agency for Health Care Administration; providing for administrative enforcement via a specified fine and permit suspension; requiring the agency to contract with an entity to designate reference price source countries and establish the reference prices for prescription drugs based on certain criteria; requiring the agency contractor to reevaluate the designated reference prices source countries annually and revised, as needed; requiring the agency contractor to weigh the reference price benchmark value of such countries in two or more tiers, using specified criteria; providing applicability; defining the term "real gross domestic product per capita"; requiring the agency contractor to analyze specified data to compare prices among source countries using a specified exchange rate source; requiring the agency contractor to establish the reference price for prescribed drugs or products; requiring such price be the lowest price after making certain adjustments;

requiring the agency contractor to update the reference prices annually and permitting reevaluation and updates at any time in certain circumstances; requiring the agency contractor to provide the reference prices by a specified date each year; requiring the agency to publish the prices online within a specified time; amending s. 465.0244, F.S.; requiring pharmacies to charge no more than the reference price for cash-paying patients; providing applicability; amending s. 627.6044, F.S.; requiring certain health insurers to provide reimbursement for certain prescription drugs no higher than the reference price; defining the term "health insurer"; providing applicability; requiring health insurers to use certain savings to offset certain payer costs; requiring each health insurer to document anticipated savings and premium reductions in rate filings following the availability of reference prices; requiring each health insurer to assess the actuarial effect of the reference pricing program for each insurer product for each plan year; requiring each health insurer to submit an annual report on the assessed effect of such program to the Office of Insurance Regulation or the Agency for Health Care Administration; providing applicability; requiring the

Office of Insurance Regulation and the Agency for Health Care Administration to submit a joint report to the Governor and the Legislature; amending s. 641.30, F.S.; requiring every health maintenance organization to comply with the provisions of a specified section; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.044, Florida Statutes, is created to read:

499.044 International Drug Reference Pricing.—

(1) It is the policy of the state that patients and third party payers in the state should not pay more for prescription drugs than those in international markets.

(2) Beginning October 1, 2025, each prescription drug manufacturer permitholder and nonresident prescription drug manufacturer permitholder shall annually report international prescription drug price data to the Agency for Health Care Administration.

(a) Permitholders shall report the actual outpatient payment or reimbursement amounts for each prescribed drug in each reference price source country identified under this subsection, including amounts paid by both third party payers such as insurers and government benefit programs and by

individual consumers not using third party payers, net of rebates and other forms of discounts. Permitholders may report the average payment amounts for each drug for a reference price source country, if weighted by utilization volume and fully documented to the agency.

(b) Permitholders may provide supplemental pricing data at any time during the year, based on a pricing in a reference price source country.

(c) Permitholders shall report the data in a format established by the agency in consultation with the contractor established under this subsection.

(d) Failure to timely report required data shall result in a fine of $10,000 a day for the first 30 days, and permit suspension thereafter until compliance is achieved.

(3) The agency shall contract with an entity to designate reference price source countries and analyze the data submitted under subsection (2) to establish the reference price for each prescribed drug or product. The agency contractor shall reevaluate the designated reference price source countries annually and revise, as needed. The agency contractor shall weigh the reference price benchmark value of the selected reference price source countries in two or more tiers, using an established index measuring the level of health care system market orientation in each country.

(a) Reference price source countries shall include only

countries with a real gross domestic product per capita of at least 40 percent of the United States gross domestic product per capita, using international sales, volume, and pricing data for each country. For the purposes of this subsection, "real gross domestic product per capita" means a country's most recent estimate based on purchasing power parity for that country available in the most recent edition of the United States Central Intelligence Agency World Factbook. Countries with single-payer health systems, which include whole-market government price-setting for prescription drugs, shall be excluded.

(b) The agency contractor shall analyze the data submitted under subsection (2) to compare prices among source countries using a publicly available, reliable, and consistent exchange rate source. The agency contractor shall establish the reference price for each prescribed drug or product, which shall be the lowest price, after adjusting for volume and difference in national gross domestic product, identified in the source countries. The agency contractor shall update the reference prices annually, and may reevaluate and update a specific reference price at any time based on a significant change documented by supplemental pricing data submitted by a manufacturer under paragraph (2)(b).

(c) The agency contractor shall provide the reference prices no later than January 1 each year, and the agency shall

publish the reference prices online within 10 days of receipt.

Section 2. Subsection (3) is added to section 465.0244, Florida Statutes, to read:

465.0244 Information disclosure and reference pricing.—

(3) A pharmacy shall charge a cash-paying patient an amount no greater that the reference price for a prescribed drug or product with a reference price established under s. 499.044. This requirement applies to product reimbursement, and does not apply to any dispensing fee.

Section 3. Subsections (3) and (4) are added to section 627.6044, Florida Statutes, to read:

627.6044 Use of a specific methodology for payment of claims.—

(3) A health insurer that provides coverage for outpatient prescribed drugs and products shall provide reimbursement for a covered prescribed drug for which there is a reference price under s. 499.044 in an amount no greater than the reference price. As used in this subsection, the term "health insurer" means an authorized insurer offering health insurance as defined in s. 624.603, the Medicaid program as established in chapter 409 and as provided in paragraph (c), the State Group Insurance Program as established in part I of chapter 110, or a health maintenance organization as defined in s. 641.19(12). This subsection applies to product reimbursement, and does not apply to any covered dispensing or administering fee established under

the terms of the provider contract.

(a) Savings generated by this subsection must be used to reduce policyholder cost sharing and premiums. Each health insurer shall document anticipated savings and premium reductions in rate filings beginning with the first rate filing following the availability of reference prices under s. 499.044.

(b) Each health insurer shall assess the actuarial effect of the reference pricing program in s. 499.044 for each insurer product for each plan year. Beginning April 1 following the first full plan year in which reference prices under s. 499.044 apply to prescription drug reimbursement, each health insurer shall submit an annual report on the assessed effect to the Office of Insurance Regulation or the Agency for Health Care Administration, as applicable.

(c) The requirements of this subsection apply to prescription drug coverage in the Medicaid program established in chapter 409 to the extent a reference price established under s. 499.044 generates greater savings for the program than that provided by the state supplemental rebate program established under s. 409.912.

(4) Beginning January 1, 2026, and annually thereafter, the Office of Insurance Regulation and the Agency for Health Care Administration shall submit a joint report to the Governor, the President of the Senate, and the Speaker of the House of Representatives detailing the impact of subsection (3) in the

preceding year, including savings realized compared to prescription drug pricing in the United States not using this pricing model, any problems encountered, barriers to access to prescription drugs, domestic and foreign prescription drug market response, monitoring and evaluating the impact on prescription drug program or plan beneficiary access, quality of care, and program costs.

Section 4. Subsection (6) is added to section 641.30, Florida Statutes, to read:

641.30 Construction and relationship to other laws.—

(6) Every health maintenance organization must comply with s. 627.6044(3).

Section 5. This act shall take effect July 1, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1639 Gender and Biological Sex
SPONSOR(S): Bankson and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation		Lloyd	Calamas
2) Insurance & Banking Subcommittee			
3) Infrastructure Strategies Committee			

SUMMARY ANALYSIS

Gender dysphoria is a behavioral health disorder diagnosable by a health care practitioner in which a person experiences incongruence between one's experienced or expressed gender and birth sex, and meets age-specific diagnostic sub-criteria. Treatment for gender dysphoria has evolved from a behavioral health approach focused on helping patients become comfortable with their biological sex, to an affirmation-focused approach potentially involving puberty blocking medication for minors and potentially cross-hormone medication and surgical interventions. Current law prohibits these services for minors, and requires informed consent for adults.

Health insurers and health maintenance organizations are regulated by the Office of Insurance Regulation and the Agency for Health Care Administration, respectively. Current law does not regulate insurance coverage of sex-reassignment prescriptions or procedures.

HB 1639 requires any health insurer or health maintenance organization coverage policy delivered in the state after July 1, 2024, which covers sex-reassignment prescriptions or procedures, to also provide coverage for treatment to de-transition from such prescriptions or procedures, for an appropriate additional premium. In addition, insurers and HMOs that offer policies with coverage for sex-reassignment prescriptions or procedures must also offer a policy that does not provide that coverage. The bill also forbids all health insurers and HMOs from prohibiting coverage of mental health or therapeutic services to treat a person's perception that his or her sex is inconsistent with the person's sex at birth by affirming the insured's sex at birth.

Current law requires driver licenses and identification cards issued by the Department of Highway Safety and Motor Vehicles (DHSMV) to include the licensee's gender, among other information; however, current law does not define "gender" or outline procedures relating to the identification of a person's gender. Current DHSMV

The bill has an insignificant negative fiscal impact on the DHSMV and no fiscal impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Gender Dysphoria

Transgender and gender nonconforming are general terms for individuals whose gender identity, role, or expression differ from their biological sex at birth.[1]

Gender dysphoria refers to the significant discomfort or distress felt as a result of the gender incongruency.[2] Gender dysphoria is a behavioral health disorder diagnosable by a health care practitioner. The American Psychiatric Association's Diagnostic Statistical Manual of Mental Disorders (DSM) classification of gender dysphoria denote a "marked incongruence between one's experienced/expressed gender and assigned[3] gender, of at least six months' duration" and manifestation of sub-criteria that differs based on age.[4]

Treatment

Treatment of gender dysphoria has evolved. Traditionally, gender identity issues were treated as a mental illness, with treatment primarily provided through psychotherapy to help patients become comfortable with their sex at birth.[5]

In the late 1990's, treatment began shifting to an "affirmative care model" after physicians in the Netherlands published a report on positive psychological outcomes for a transgender adolescent treated with hormones.[6] Those physicians suppressed puberty in the early stages followed by cross-sex hormone therapy starting at age 16. This treatment model became known as the "Dutch Protocol".

The "Dutch Protocol", as well as the re-categorization of gender identity issues in the DSM, created a profound shift in the medically accepted treatment for gender issues. In 2013, the authors of the DSM replaced the term "gender identity disorder" with "gender dysphoria in children" and "gender dysphoria in adolescence and adults" to diagnose and treat the distress individuals felt by the incongruency between their gender identities and their bodies.[7] The medical community stopped classifying gender identity issues as a mental illness. The "Dutch Protocol" was subsequently incorporated into the widely adopted standards of care for the treatment of transgender patients.[8]

The treatment goal now focuses on affirming the patient's gender identity rather than affirming the gender of the patient's sex at birth. Treatment for gender dysphoria now primarily addresses the

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[1] Coleman, E., Radix, A.E., Bouman, W.P., Brown, G.R., de Vries, A.L.C., et al, (2022), Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, International Journal of Transgender Health*, 23(S1), S1-S260.
[2] *Id*.
[3] The DSM uses "assigned" to refer to the delivery physician's assessment and notation of the child's biological sex, usually based on external genitalia. See, American Psychiatric Association, Gender Dysphoria, available at, https://www.psychiatry.org/patients-families/gender-dysphoria (last viewed May 10, 2023).
[4] American Psychiatric Association, (2013), Diagnostic and Statistical Manual of Mental Disorders (5th ed.), Arlington, VA: American Psychiatric Publishing.
[5] *See* Diagnostic and statistical manual of mental disorders. 3rd ed. Washington, DC: American Psychiatric Publishing; 1980; Diagnostic and statistical manual of mental disorders. 4th ed. Washington, DC; American Psychiatric Publishing; 1994.
[6] Cohen-Kettenis P.T., van Goozen S.H., (1998), Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent, *Eur Child Adolsc. Psychiatry*, 7(4):246-8.
[7] The American Psychiatric Association stated that "it is important to note that gender nonconformity is not itself a mental disorder". *Supra* note 4.
[8] *Supra* note 2; Hembree, W., Cohen-Kettenis, P., et al, (2017), Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *Journal of Clinical Endocrinology & Metabolism*, 102(11):2896-3903.

incongruency with psychotherapy and medical interventions that align the body with the mind, rather than the mind with the body. This treatment may include:[9]

- Psychotherapy to address the negative impact of gender dysphoria and mental health, which includes social transitioning to affirm an individual's felt gender identity, role, and expression.
- Puberty blockers to suppress the release of testosterone or estrogen and stop the onset of secondary sex characteristics.
- Cross-sex hormone therapy to feminize or masculinize the body.
- Sex reassignment surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalize, facial features, and body contouring).

Concerns with Treatment

Clinicians and academics have raised concerns with the appropriateness of medical interventions for minors based on the lack of rigorous scientific research on the issue. Various issues bring the value of gender treatment research into question, specifically: many lack randomized control trials, use small sample sizes, and have a medium to high risk of bias due to recruitment design.[10] From the perspective of some clinicians, there are no studies that sufficiently evaluate the long-term impact of medical treatments, so the long-term effects on physical developments, fertility, sexual function and brain development is unknown.[11]

Limited research suggest access to puberty blockers and gender-affirming hormones may improve mental health outcomes, including reduced anxiety, depression, self-harm, and suicidality, in the short-term.[12] On the other hand, other research found a higher rate of suicide attempts and suicide completion in the short term, and much higher rates of suicide compared to the general population beginning 10 years post-transition.[13]

Researchers are just beginning to understand the unintended physical effects of transgender treatment. Puberty is a time of complex chemical changes that direct the development of many bodily functions. Taking puberty blockers at that time can prevent that development, with the possibility of significant future harms as an adult. For example, recent studies document the effect of puberty-blocking medications on bone development, causing severe lack of density, which may be irreversible.[14] The long-term effect of puberty blockers and cross-sex hormone treatment on sexual function in adulthood requires further research. One literature review noted both positive and negative effects, but also noted that there is no valid tool to accurately measure sexual health outcomes.[15] Similarly, researchers are beginning to express concerns about the impact on the brain, including permanent alterations to neurodevelopment. [16]

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[9] *Supra* note 3.
[10] *See* Hruz, P., (2019), Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, *The Linacre Quarterly* 87:1, 34-42.; Abbruzzese, E., Levine, S., Mason, J., (2023), The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies – and research that has followed, *Journal of Sex & Martial Therapy* DOI: 10.1080/0092623X.2022.2150346.
[11] *Supra* note 9.
[12] *See* Allen, L. R., Watson, L. B., Egan, A. M., Moser, C. N., (2019), Well-being and suicidality among transgender youth after gender-affirming hormones, *Clinical Practice in Pediatric Psychology*, 7(3), 302.
[13] Dhejne C., Lichtenstein, P., Boman M., Johansson A., Långström N., Landén, M., (2011), Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden, *PLoS One*, vol. 6, issue 2.
[14] See, e.g., Joseph T, Ting J, Butler G. The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: Findings from a large national cohort. *J Pediatr Endocrinol Metab*. 2019; 10: 1077– 1081; Lee J., et al, (2020), Low bone mineral density in early pubertal transgender/gender diverse youth: findings from the trans youth care study, *J Endocr Soc*. Sep 1; 4(9): bvaa065. In 2022, the Endocrine Society took the position that more research is needed in this area to properly address bone health in young patients. Endocrine Society, "Longer treatment with puberty-delaying medication in transgender youth leads to lower bone mineral density", June 12, 2022, available at https://admin.endocrine.org/news-and-advocacy/news-room/2022/longer-treatment-with-puberty-delaying-medication-leads-to-lower-bone-mineral-density (last viewed January 20, 2024).
[15] Mattawanon N., Charoenkwan K., Tangpricha V., (2021), Sexual dysfunction in transgender people: a systematic review, *Urol Clin N Am* 48 (2021) 437–460. See, Shirazi TN, Self H, Dawood K, et al., Pubertal timing predicts adult psychosexuality: Evidence from typically developing adults and adults with isolated GnRH deficiency, *Psychoneuroendocrinology*. 2020; 104733:104733;
[16] See, e.g.,Chen D, Strang JF, Kolbuck VD, et al. Consensus parameter: Research methodologies to evaluate neurodevelopmental effects of pubertal suppression in transgender youth. *Transgender Health*. 2020; 4: 246– 257.

Regulation of Sex-Reassignment Prescriptions and Procedures in Florida

Current law regulates sex-reassignment prescriptions and procedures as a matter of practitioner licensure. These prescriptions and procedures include:[17]

- Puberty blockers prescribed to stop or delay normal puberty in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex;[18]
- Hormones or hormone antagonists prescribed to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex; and
- Medical procedures to affirm a person's perception of his or her sex if that perception is inconsistent the person's sex.

Current law prohibits sex-reassignment prescriptions and procedures for patients under age 18, with exceptions for minors actively receiving this treatment at the time the law was enacted in 2023. For adults, physicians must obtain specified informed consent on a form adopted by the Boards of Medicine and Osteopathic Medicine.[19]

Regulation of Insurers and Health Maintenance Organizations

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk bearing entities in Florida.[20] The Agency for Health Care Administration (AHCA) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[21]

All persons who transact insurance in this state must comply with the Code.[22] The OIR has the authority to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[23] and may investigate any matter relating to insurance.[24]

A health insurance mandate is a legal requirement that an insurance company or health plan cover specific benefits, or services by particular health care providers, or specific patient groups. A contingent coverage mandate requires coverage of a service, condition, or provider's care *only if* coverage is provided for a certain other service, condition, or provider's care. In general, coverage mandates increase the cost of health coverage in varying amounts depending on the cost of the mandated care and the amount of patient utilization of that care.

Mandated offerings, on the other hand, do not mandate that certain benefits be provided. Rather, a mandated offering law requires that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require an additional premium and which the consumer is free to accept or reject.

Current Florida law requires every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurer, to submit to the Agency for Health Care Administration and the legislative committees having jurisdiction, a report that assesses the social and financial impacts of the proposed coverage.[25] To the extent information is available, the report should address:

[17] S. 456.08, F.S.
[18] Under current law, a person's sex is indicated by a person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth. S. 456.001(8), F.S.
[19] S. 456.52, F.S.
[20] S. 20.121(3)(a), F.S.
[21] S. 641.21(1)(1), F.S.
[22] S. 624.11, F.S.
[23] S. 624.307(4), F.S.
[24] S. 624.307(3), F.S.
[25] S. 624.215, F.S.

- The extent to which the treatment or service is generally used by a significant portion of the population.
- The extent to which insurance coverage is generally available; or, if not generally available, results in persons avoiding necessary health care treatment.
- The extent to which lack of coverage results in unreasonable financial hardship.
- The level of public demand for the treatment or service.
- The level of public demand for insurance coverage of the treatment or service.
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.
- The extent to which coverage will increase or decrease the cost of the treatment or service.
- The extent to which coverage will increase the appropriate uses of the treatment or service.
- The extent to which the treatment or service will be a substitute for a more expensive treatment or service.
- The extent to which the coverage will increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.
- The impact of this coverage on the total cost of health care.

The House Health and Human Services Committee has not received a report for HB 1639.

Currently, the Code does not regulate coverage of sex-reassignment prescriptions or procedures. The extent to which health insurers and HMOs provide coverage for sex-reassignment prescriptions or procedures is unknown.

State Driver Licenses and Identification Cards

Under Florida law, an application for the issuance of an identification card or a driver license from the Department of Highway Safety and Motor Vehicles (DHSMV) must include certain information, including the applicant's gender.[26] Additionally, a printed driver license issued by DHSMV to a driver must include, among other requirements, a licensee's gender and a space upon which the licensee shall affix his or her usual signature.[27] Florida law does not define "gender" in the context of driver license and identification card issuance.

Although not expressed in Florida law, the DHSMV Driver License Operations Manual governs how gender is determined for purposes of driver licenses and identification cards. Primarily, an applicant's gender is taken from the primary identification document, such as a birth certificate or a valid and non-expired United States passport. If a primary identification document does not list a gender, then the customer would specify which gender they most closely identify with for the use of the credential. Similarly, if the primary identification document indicates "nonbinary X" for gender, and the applicant presents no other primary resource documentation indicating gender, then the applicant would specify the gender they must closely identify with on the application.[28]

To change a gender on a driver license or identification card[29], an applicant can present a credential from another state with the desired gender, a certified court order, or a signed statement on office letterhead from a physician or advanced practice nurse meeting certain criteria. The statement must include language stating that the applicant is undergoing clinical treatment for gender transition, and language declaring under penalty of perjury that the statement is true and correct.[30] The DHSMV follows standards established by the World Professional Association for Transgender Health.[31]

Effects of the Bill

[26] Ss. 322.051(1), F.S. and 322.08(2)(a), F.S.
[27] S. 322.14(1)(a), F.S.
[28] Florida Department of Highway Safety and Motor Vehicles, *Driver License Operations Manual, IR08.3 - Establishing Gender*.
[29] Other than for a clerical error.
[30] Florida Department of Highway Safety and Motor Vehicles, *Driver License Operations Manual, IR08.4 - Gender Change.*
[31] *Id*. at p. 2

State Driver Licenses and Identification Cards

The bill replaces the statutory term “gender” with the term “sex”, as it relates to driver license and identification card issuance. Specifically, the bill provides that an application for the issuance of an identification card or a driver license from DHSMV must include certain information, including the applicant’s sex. Additionally, the bill requires printed driver licenses issued by DHSMV to a driver to include the licensees’ sex rather than gender.

DHSMV will be required to amend operational policies to reflect these changes, which under the bill must require the applicant’s sex to be identified, rather than gender.

Regulation of Insurers and Health Maintenance Organizations

The bill authorizes insurers and HMOs to cover sex-reassignment prescriptions and procedures, for an additional premium, but imposes a contingent coverage mandate related to sex-reassignment coverage: a health insurer or HMO which covers sex-reassignment prescriptions or procedures must also cover treatment to treatments to de-transition from such prescriptions or procedures.

The impact of this provision is unclear, because the extent of sex-reassignment prescriptions or procedures coverage, and de-transition coverage, is unknown. Health insurers and HMOs providing both types of coverage will not be affected by the bill; similarly, those not providing covering for sex-reassignment prescriptions or procedures will be unaffected. Insurers and HMOs providing coverage for sex-reassignment prescriptions or procedures only, without de-transition coverage, may comply with the conditional mandate by either providing de-transition coverage, for an additional cost, or by eliminating coverage for sex-reassignment prescriptions or procedures (thereby eliminating the pre-condition that triggers the contingent mandate).

The bill also imposes a mandated offering: an insurer or HMO which issues a policy that provides coverage for sex-reassignment prescriptions and procedures must also offer a policy that does not provide such coverage. Again, it is unknown how many health insurers and HMOs issue policies that provide this coverage and so would be subject to the requirement to offer policies that do not cover it.

Finally, the bill forbids health insurers and HMOs from prohibiting coverage of mental health and therapeutic services to treat a person’s perception that his or her sex is inconsistent with sex at birth by affirming the person’s sex at birth.

The bill provides and effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends 322.051, F.S.; relating to identification cards.
Section 2: Amends 322.08, F.S.; relating to application for licenses and identification cards.
Section 3: Amends 322.14, F.S.; relating to licenses issued to drivers.
Section 4: Creates 627.411, F.S.; relating to coverage for sex-assignment prescriptions or procedures.
Section 5: Amends 627.657, F.S; relating to provisions of group health insurance policies.
Section 6: Amends 627.6699, F.S.; relating to Employee Health Care Access Act.
Section 7: Amends 641.31, F.S; relating to health maintenance contracts.
Section 8: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

   The bill has an insignificant fiscal impact on DHSMV for administrative costs to update driver license and identification card applications and printed driver licenses to refer to “sex” instead of “gender” and updating the operational manual, which can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

2. Not applicable. This bill does not appear to affect county or municipal governments.

3. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have an indeterminate, negative fiscal impact on health insurers and HMOs, depending on their current coverage options and offerings. Practitioners and facilities may experience an increase or decrease in demand for such services, depending on the extent of current coverage and the market response of health insurers and HMOs to the bill’s provisions.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments

2. Other:

   The bill appears to make the contingent coverage mandate provision effective July 1, 2024, which may implicate the impairment of contract provisions of Art. 1 Sec. X of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority for OIR, AHCA and DHSMV to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

To avoid implicating the provisions of Art. 1 Sec. X of the Florida Constitution, the bill could be amended to make the insurance provisions effective for contracts entered into or renewed after January 1, 2025.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to gender and biological sex; amending ss. 322.051, 322.08, and 322.14, F.S.; requiring applications for driver licenses and identification cards, as well as printed driver licenses, to indicate a person's sex instead of his or her gender; creating s. 627.6411, F.S.; requiring health insurance policies that include coverage for sex-reassignment prescriptions or procedures to also provide coverage for certain detransition treatments; requiring health insurers providing such coverage to also offer insurance policies that do not provide such coverage; prohibiting health insurance policies from prohibiting coverage of certain mental health and therapeutic services; amending ss. 627.657, 627.6699, and 641.31, F.S.; requiring group health insurance policies, health benefit plans, and health maintenance contracts that include coverage for sex-reassignment prescriptions or procedures to also provide coverage for certain detransition treatments; requiring group health insurers, carriers, and health maintenance organizations providing such coverage to also offer insurance policies that do not provide such coverage; prohibiting group health insurance policies, health benefit plans, and health maintenance contracts from

prohibiting coverage of certain mental health and therapeutic services; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (1) of section 322.051, Florida Statutes, is amended to read:

322.051 Identification cards.—

(1) Any person who is 5 years of age or older, or any person who has a disability, regardless of age, who applies for a disabled parking permit under s. 320.0848, may be issued an identification card by the department upon completion of an application and payment of an application fee.

(a) The application must include the following information regarding the applicant:

1. Full name (first, middle or maiden, and last), sex ~~gender~~, proof of social security card number satisfactory to the department, which may include a military identification card, county of residence, mailing address, proof of residential address satisfactory to the department, country of birth, and a brief description.

2. Proof of birth date satisfactory to the department.

3. Proof of identity satisfactory to the department. Such proof must include one of the following documents issued to the applicant:

a. A driver license record or identification card record from another jurisdiction that required the applicant to submit a document for identification which is substantially similar to a document required under sub-subparagraph b., sub-subparagraph c., sub-subparagraph d., sub-subparagraph e., sub-subparagraph f., sub-subparagraph g., or sub-subparagraph h.;

b. A certified copy of a United States birth certificate;

c. A valid, unexpired United States passport;

d. A naturalization certificate issued by the United States Department of Homeland Security;

e. A valid, unexpired alien registration receipt card (green card);

f. A Consular Report of Birth Abroad provided by the United States Department of State;

g. An unexpired employment authorization card issued by the United States Department of Homeland Security; or

h. Proof of nonimmigrant classification provided by the United States Department of Homeland Security, for an original identification card. In order to prove nonimmigrant classification, an applicant must provide at least one of the following documents. In addition, the department may require applicants to produce United States Department of Homeland Security documents for the sole purpose of establishing the maintenance of, or efforts to maintain, continuous lawful presence:

(I) A notice of hearing from an immigration court scheduling a hearing on any proceeding.

(II) A notice from the Board of Immigration Appeals acknowledging pendency of an appeal.

(III) A notice of the approval of an application for adjustment of status issued by the United States Citizenship and Immigration Services.

(IV) An official documentation confirming the filing of a petition for asylum or refugee status or any other relief issued by the United States Citizenship and Immigration Services.

(V) A notice of action transferring any pending matter from another jurisdiction to Florida, issued by the United States Citizenship and Immigration Services.

(VI) An order of an immigration judge or immigration officer granting relief that authorizes the alien to live and work in the United States, including, but not limited to, asylum.

(VII) Evidence that an application is pending for adjustment of status to that of an alien lawfully admitted for permanent residence in the United States or conditional permanent resident status in the United States, if a visa number is available having a current priority date for processing by the United States Citizenship and Immigration Services.

(VIII) On or after January 1, 2010, an unexpired foreign passport with an unexpired United States Visa affixed,

accompanied by an approved I-94, documenting the most recent admittance into the United States.

An identification card issued based on documents required in sub-subparagraph g. or sub-subparagraph h. is valid for a period not to exceed the expiration date of the document presented or 1 year, whichever occurs first.

Section 2. Paragraph (a) of subsection (2) of section 322.08, Florida Statutes, is amended to read:

322.08 Application for license; requirements for license and identification card forms.—

(2) Each such application shall include the following information regarding the applicant:

(a) Full name (first, middle or maiden, and last), sex ~~gender~~, proof of social security card number satisfactory to the department, which may include a military identification card, county of residence, mailing address, proof of residential address satisfactory to the department, country of birth, and a brief description.

Section 3. Paragraph (a) of subsection (1) of section 322.14, Florida Statutes, is amended to read:

322.14 Licenses issued to drivers.—

(1)(a) The department shall, upon successful completion of all required examinations and payment of the required fee, issue to every qualified applicant a printed driver license that must

bear a color photograph or digital image of the licensee; the name of the state; a distinguishing number assigned to the licensee, which, beginning November 1, 2023, must have a minimum of four randomly generated digits on each original, renewal, or replacement driver license; and the licensee's full name, date of birth, and residence address; a brief description of the licensee, including, but not limited to, the licensee's sex ~~gender~~ and height; and the dates of issuance and expiration of the license. A space shall be provided upon which the licensee shall affix his or her usual signature. A license is invalid until it has been signed by the licensee except that the signature of the licensee is not required if it appears thereon in facsimile or if the licensee is not present within the state at the time of issuance.

Section 4. Section 627.6411, Florida Statutes, is created to read:

627.6411 Coverage for sex-reassignment prescriptions or procedures.—

(1) A health insurance policy that is delivered or issued to a person in the state may offer, for an appropriate additional premium, coverage for sex-reassignment prescriptions or procedures, as defined in s. 456.001, only if the same health insurance policy also provides coverage for treatment to detransition from the sex-reassignment prescriptions or procedures.

(2) A health insurer that delivers or issues a health insurance policy that provides coverage described under subsection (1) must also offer a health insurance policy that does not provide such coverage.

(3) A health insurance policy that is delivered or issued to a person in the state may not prohibit the coverage of mental health or therapeutic services to treat a person's perception that his or her sex, as defined in s. 456.001, is inconsistent with such person's sex at birth by affirming the insured's sex.

Section 5. Subsections (4) and (5) are added to section 627.657, Florida Statutes, to read:

627.657 Provisions of group health insurance policies.—

(4)(a) A group health insurance policy that is delivered or issued to any group in the state may offer, for an appropriate additional premium, coverage for sex-reassignment prescriptions or procedures, as defined in s. 456.001, only if the same group health insurance policy also provides coverage for treatment to detransition from the sex-reassignment prescriptions or procedures.

(b) A group health insurer that delivers or issues a group health insurance policy that provides coverage described under paragraph (a) must also offer a group health insurance policy that does not provide such coverage.

(5) A group health insurance policy that is delivered or issued to any group in the state may not prohibit the coverage

of mental health or therapeutic services to treat a person's perception that his or her sex, as defined in s. 456.001, is inconsistent with such person's sex at birth by affirming the insured's sex.

Section 6. Paragraphs (h) and (i) are added to subsection (5) of section 627.6699, Florida Statutes, to read:

627.6699 Employee Health Care Access Act.—

(5) AVAILABILITY OF COVERAGE.—

(h)1. A health benefit plan that is delivered or issued to an individual or a group in the state may offer, for an appropriate additional premium, coverage for sex-reassignment prescriptions or procedures, as defined in s. 456.001, only if the same health benefit plan also provides coverage for treatment to detransition from the sex-reassignment prescriptions or procedures.

2. A carrier that delivers or issues a health benefit plan that provides coverage described under subparagraph 1. must also offer a health benefit plan that does not provide such coverage.

(i) A health benefit plan that is delivered or issued to an individual or a group in the state may not prohibit the coverage of mental health or therapeutic services to treat a person's perception that his or her sex, as defined in s. 456.001, is inconsistent with such person's sex at birth by affirming the insured's sex.

Section 7. Subsections (48) and (49) are added to section

641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(48)(a) A health maintenance contract that is delivered or issued to a subscriber or group in the state may offer, for an appropriate additional premium, coverage for sex-reassignment prescriptions or procedures, as defined in s. 456.001, only if the same health maintenance contract also provides coverage for treatment to detransition from the sex-reassignment prescriptions or procedures.

(b) A health maintenance organization that delivers or issues a health maintenance contract that provides coverage described under paragraph (a) must also offer a health maintenance contract that does not provide such coverage.

(49) A health maintenance contract that is delivered or issued to a subscriber or group in the state may not prohibit the coverage of mental health or therapeutic services to treat a person's perception that his or her sex, as defined in s. 456.001, is inconsistent with such person's sex at birth by affirming the insured's sex.

Section 8. This act shall take effect July 1, 2024.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Select Committee on Health Innovation

Representative Tramont offered the following:

Amendment (with title amendment)

Between lines 30 and 31, insert:

Section 1. Subsection (49) is added to section 322.01, Florida Statutes, to read:

322.01 Definitions.—As used in this chapter:

(49) "Sex" means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth.

T I T L E A M E N D M E N T

Remove line 3 and insert:

s. 322.021; creating a definition; amending ss. 322.051, 322.08, and 322.14, F.S.; requiring