The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1084
INTRODUCER:	Banking and Insurance Committee and Senator Gaetz
SUBJECT:	Health Care Protocols
DATE:	January 20, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.			HP	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1084 creates the "Right Medicine, Right Time Act." Timely access to health care can be a significant issue for anyone with an illness, but it is particularly critical for individuals who have conditions with the potential to cause death, disability, or serious discomfort unless treated with the most appropriate medical care. Generally, step-therapy or fail-first protocols for prescription drugs coverage require an insured or enrollee to try a certain drug, usually a generic alternative, before receiving coverage for another drug, usually a branded, and more expensive product.

The bill requires Medicaid managed care plans, health maintenance organizations (HMOs), and insurers that restrict medications by a step-therapy or fail-first protocol to have a clear and convenient process to request an override of the protocol. The bill requires these entities to grant an override of the protocol within 24 hours if, based on sound clinical evidence or medical and scientific evidence, the prescribing provider:

- Concludes that the preferred treatment required under the fail-first protocol has been ineffective in the treatment of the enrollee's disease or medical condition; or
- Believes that the preferred treatment required under the fail-first protocol is likely to be ineffective given the known relevant physical or mental characteristics and medical history of the enrollee and the known characteristics of the drug regimen or will cause or is likely to cause an adverse reaction or other physical harm to the enrollee.

The bill requires that the duration of treatment may not exceed a period deemed appropriate by the prescribing provider, if the provider follows the fail-first protocol recommended by the

managed care plan for an enrollee. Following such period, if the prescriber deems the treatment provided under the protocol clinically ineffective, the enrollee is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol.

The bill prohibits an HMO from requiring a health care provider to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making relating to the use of such services. Advocates of clinical decision support systems and laboratory benefits management programs contend that these programs were developed to improve affordability and quality of care for enrollees and avoid errors and adverse events. Some opponents of these programs contend that these applications impinge upon medical judgment of the health care provider, cause delays in providing care, and increase costs.

II. Present Situation:

Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[1] The Agency for Health Care Administration (agency) regulates the quality of care provided 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 the agency.[2] As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[3]

Florida's Statewide Medicaid Managed Care

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. In Florida, the Agency for Healthcare Administration (AHCA) administers the program. In 2013 and 2014, the agency implemented the legislatively mandated Statewide Medicaid Managed Care (SMMC) program. The SMMC program has two components: the Managed Medicaid Assistance (MMA) program and the Long-term Care program. The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in August 2014. Most Florida Medicaid recipients who are eligible for the full array of Florida Medicaid benefits are enrolled in an MMA plan.

Managed care plans have the ability to implement service authorization and utilization management requirements for the services they provide under the SMMC program. However, Medicaid managed care plans are required to ensure that: service authorization decisions are based on objective evidenced-based criteria, utilization management procedures are applied consistently, and all decisions to deny or limit a requested service are made by health care professionals who have the appropriate clinical expertise in treating the enrollee's

[1] Section 20.121(3)(a), F.S.
[2] Section 641.21(1), F.S.
[3] Section 641.495, F.S.

condition/disease. The managed care plans are also required to adopt practice guidelines that are based on valid and reliable clinical evidence or a consensus of health care professionals in a particular field; consider the needs of the enrollees; are adopted in consultation with providers; and are reviewed and updated periodically, as appropriate. These guidelines are consistent with requirements found in federal regulations.[4]

The AHCA maintains coverage and limitations policies for most Florida Medicaid services. Medicaid managed care plans cannot be more restrictive than these policies or the Florida Medicaid State Plan (which is approved by the federal Centers for Medicare and Medicaid Services or CMS) in providing services to their enrollees. Managed care plans must notify enrollees and providers of the services they provide and inform them of any prior authorization requirements or coverage limitations in their respective handbooks.

Section 409.91195, F.S., establishes the Pharmaceutical and Therapeutics (P&T) committee within the AHCA for the development of a Florida Medicaid preferred drug list (PDL). The P&T committee meets quarterly, reviews all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the AHCA's Florida Medicaid PDL, such that the PDL provides for medically appropriate drug therapies for Florida Medicaid recipients and an array of choices for prescribers within each therapeutic class. The AHCA also manages the federally required Medicaid Drug Utilization Board, which meets quarterly, develops, and reviews clinical prior authorization criteria, including step-therapy protocols for drugs that are not on the AHCA's Florida Medicaid PDL.

Managed care plans serving MMA enrollees are required to provide all prescription drugs listed on the AHCA's Florida Medicaid PDL for at least the first year of operation.[5] As such, the managed care plans have not implemented their own plan-specific formulary or PDL. The managed care plan's prior authorization criteria/protocols related to prescribed drugs cannot be more restrictive than the criteria established by the AHCA. The AHCA posts prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the AHCA's Internet Web site within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the AHCA, in accordance with s. 409.912, F.S. MMA plans may adopt the Florida Medicaid prior authorization criteria or develop their own criteria. Prior authorization and step-therapy protocols for PDL may not be more restrictive than protocols posted on the AHCA's website.[6]

Section 409.967, F.S., currently requires managed care plans to publish any prescribed drug formulary or PDL on the plan's Web site 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

[4] 42 CFR s. 438.236(b).
[5] See SMMC Plans, Model Contract, Attachment II, Core Contract Provisions, page 45, effective November 1, 2015, at: http://ahca.myflorida.com/Medicaid/statewide_mc/plans.shtml and the Pharmacy Snapshot at: https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/Pharmacy_Snapshot_2014-08-27.pdf (last visited Jan. 14, 2016).
[6] Agency for Health Care Administration *Senate Bill 1084 Analysis* (Jan.13, 2016) (on file with the Senate Committee on Banking and Insurance).

accessible to health care providers, including posting appropriate contact information on its Web site and providing timely responses to providers.

Florida' State Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with section 125, Internal Revenue Code. To administer the state group health insurance program, the DMS contracts with third party administrators, HMOs, and a pharmacy benefits manager (PBM) for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

The health plan administrators, HMOs and PBM each have their respective clinical coverage guidelines and utilization management practices to ensure appropriateness of care and to manage plan costs. These coverage guidelines are based on clinical evidence and recommendations from clinical and pharmacy and therapeutics committees comprised of practicing physicians and pharmacists. The National Committee for Quality Assurance and other national accreditation organizations define the structure and function of these committees, which have the same duties described for the proposed commission.

The state employees' self-insured prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list). Contractually the PBM for the state employees' self-insured prescription drug program updates the preferred drug list quarterly as brand drugs enter the market and as the PBM negotiates pricing, including rebates with manufacturers.[7]

Federal Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[8] The PPACA provides fundamental changes to the U.S. health care system by requiring health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA imposes many insurance requirements including required essential health benefits, rating and underwriting standards, review of rate increases, and internal and external appeals of adverse benefit determinations.[9]

[7] Footnote 1A of s.110.12315, F.S., prohibits the state's prescription drug program from implementing a prior authorization program or step-therapy program for non-HMO members. Step-therapy is currently not in place for any state-group health plan member.

[8] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. P.L. 111-148.

[9] Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), (42 U.S.C. 300gg *et seq*.).

Qualifying coverage may be obtained through an employer, the federal or state marketplaces or exchanges created under PPACA, or private individual or group coverage meeting the minimum essential benefits coverage standard off the exchange. Florida did not establish its own state exchange under PPACA. Premium credits and other cost sharing subsidies are available to U.S. citizens and legal immigrants within certain income limits for qualified coverage purchased through the exchange. Premium credits are set on a sliding scale based on a percentage of the federal poverty level and reduce the out-of-pocket costs incurred by individuals and families.

Prior to an insurer offering a plan through an exchange, an exchange must certify that the plan meets certain federal essential health benefits and other requirements to be deemed a qualified health plan (QHP). Section 1302 of the Affordable Care Act requires QHPs to provide coverage of essential health benefits (EHB), meet cost-sharing limits and actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, which includes prescription drugs.[10]

Final HHS Notice of Benefit and Payment Parameters for 2016

On March 20, 2014, the final HHS regulations relating to notice of benefit and payment parameters was released, which establishes key standards for issuers and marketplaces for 2016. These regulations include provisions relating to prescription drug coverage, formulary drug lists, and the drug exception process.[11]

Prescription Drug Coverage. Currently, for purposes of complying with the essential health benefits, insurers and HMOs must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's essential health benefit (EHB) benchmark plan. For plan years beginning on or after January 1, 2017, plans must also use a P&T committee process that meets certain requirements. The P&T committee must design formularies using scientific evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines.[12]

Formulary Drug List. The regulations require a health plan must publish an up-to-date and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the marketplace, HHS, and the public. Additionally, insurers and HMOs must also make this information available in a standard-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Drug Exceptions Process. Under current HHS regulations, plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not included on the plan's formulary drug list. Such procedures must include a process to

[10] See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Jan.14, 2016) for Florida's benchmark plan.
[11] HHS, *Final HHS Notice of Benefit and Payment Parameters for 2016*, Factsheet, at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2016-PN-Fact-Sheet-final.pdf (last visited Jan. 10, 2016).
[12] 45 CFR s. 156.122.

request an expedited review based on exigent circumstances. Under this expedited process, the issuer must make its coverage determination no later than 24 hours after it receives the request. This requirement, commonly referred to as the "exceptions process," applies to drugs that are not included on the plan's formulary drug list. For plan years beginning in 2016, these processes must also include certain processes and timeframes for the standard review process, and have an external review process if the internal review request is denied. The costs of the non-formulary drug provided through the exceptions process count towards the annual limitation on cost sharing and actuarial value of the plan.[13]

Cost Containment Measures Used by Insurers and HMOs

Prior Authorization and Step Therapy or Fail First Therapy

Insurers use many cost containment and utilization review strategies to manage medical and drug spending and patient safety. For example, plans may place utilization management requirements on the use of certain drugs on their formulary. This may include requiring enrollees to obtain prior authorization from their plan before being able to fill a prescription, requiring enrollees to try first a preferred drug to treat a medical condition before being able to obtain an alternate drug for that condition, or limiting the quantity of drugs that they cover over a certain period.

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. A PDL is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. In order to obtain another drug within the therapeutic class, not part of the PDL, prior authorization is required. Prior authorization for emergency services is not required. Preauthorization for hospital inpatient services is generally required.

In some cases, plans require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe Drug A first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. Advocates of step therapy state that a step therapy approach requires the use of a clinically recognized first-line drug before approval of a more complex and often more expensive medication where the safety, effectiveness, and values has been well established before a second-line drug is authorized.

According to a published report by researchers affiliated with the National Institutes of Health, there is mixed evidence on the impact of step therapy policies.[14] A review of the literature by Brenda Motheral found that there is little good empirical evidence,[15] but other studies[16] suggest

[13] 45 C.F.R. s. 156.122(c). The drug exception process is distinct from the coverage appeals process, which applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. The coverage appeals process has separate requirements for its external review process and allows for a secondary level of internal review before the final internal review determination for group plans. [45 C.F.R. s. 147.136]

[14] The Ethics Of "Fail First": Guidelines and Practical Scenarios for Step Therapy Coverage Policies, Rahul K. Nayak and Steven D. Pearson *Health Affairs* 33, No.10 (2014):1779-1785.

[15] Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature, Brenda R. Motheral, *Journal of Managed Care Pharmacy* 17, no. 2 (2011) 143-55.

[16] See fn. 14 at pg. 1780.

that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services. However, some studies have found that the policies can increase total utilization costs over the long run because of increased inpatient admissions and emergency department visits.[17] One-step therapy policy for a typical antipsychotic medication in a Medicaid program was associated with a higher rate of discontinuity in medication use, an outcome that was linked to increased risk for hospitalization.[18]

Clinical Decision Support Systems and Laboratory Benefit Management Programs

Clinical decision support (CDS) systems are designed to improve clinical decision-making and to provide a platform for integrating evidence based knowledge into health care delivery.[19] The CDS systems encompass a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.

Laboratory Benefit Management Programs. The Laboratory Benefit Management Program (program) [20] was developed to help manage appropriate utilization for outpatient laboratory services.[21] A pilot program, instituted in 2014, is limited to fully insured commercial members in Florida, excluding Neighborhood Health Partnership members. As part of the program, all outpatient laboratory services for these members are subject to new requirements including advance notification and new medical policies. If a provider orders laboratory services and their practice is located in Florida, the provider must use BeaconLBS Physician Decision Support when ordering any of the Decision Support Tests for members who are part of the program. The Physicians Decision Support system is an online tool that helps physicians select tests and laboratories using evidence-based guidelines and following insurer's policies. These tests are listed in the administrative protocol.

Associations that represent health care providers have expressed concerns about the negative impact that this electronic decision support program will have on the quality of and access to care for patients.[22] In particular, some have stated that the program interferes with the physician relationship and does not improve health care quality or access to care. These interactions, they argue, redirect valuable time and resources away from patients and add to a growing administrative burden that threatens the practice of medicine.[23]

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[17] See *id*.
[18] See *id*.
[19] See https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds (last visited January 15, 2016).
[20] Beacon Laboratory Benefit Solutions, Inc. (BeaconLBS®), a subsidiary of LabCorp®, administers the Laboratory Benefit Management Program for UnitedHealthcare.
[21] UnitedHealthcare, *UnitedHealthcare Laboratory Benefit Management Program Frequently Asked Questions* (Jun. 29, 2015) (on file with Senate Committee on Banking and Insurance).
[22] James L. Madara, M.D., correspondence with UnitedHealth Group (Mar. 18, 2015) (on file with Senate Banking and Insurance Committee).
[23] Allen Pillersdorf, M.D., correspondence with UnitedHealthcare (on file with Senate Banking and Insurance Committee).

III. Effect of Proposed Changes:

Section 1 states that the act may be known as the "Right Medicine Right Time Act."

Sections 2, 3, and 5 amends s. 409.967, and creates ss. 627.42392, and 641.394, F.S., respectively, relating to Medicaid managed care plans, insurers, and HMOs, that utilize a fail-first protocol. The bill require Medicaid managed care plans, HMOs, and insurers that restrict medications by a step-therapy or fail-first protocol to have a clear and convenient process to request an override of the protocol. The bill requires these entities to grant an override of the protocol within 24 hours if, based on sound clinical evidence or medical and scientific evidence, the prescribing provider:

- Concludes that the preferred treatment required under the fail-first protocol has been ineffective in the treatment of the enrollee's disease or medical condition; or
- Believes that the preferred treatment required under the fail-first protocol is likely to be ineffective given the known relevant physical or mental characteristics and medical history of the enrollee and the known characteristics of the drug regimen, or will cause or is likely to cause an adverse reaction or other physical harm to the enrollee.

The bill requires that the duration of treatment may not exceed a period deemed appropriate by the prescribing provider, if the provider follows the fail-first protocol recommended by the managed care plan for an enrollee. Following such period, if the prescriber deems the treatment provided under the protocol clinically ineffective, the enrollee is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol.

Section 4 of the bill amends s. 641.31, F.S., to prohibit an HMO from requiring a health care provider to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making relating to the use of such services. The term, "clinical decision support system," means software designed to direct or assist clinical decision-making by matching the characteristics of an individual patient to a computerized clinical knowledge base and providing patient-specific assessments or recommendations based on the match. The term, "laboratory benefits management program," means an HMO protocol that dictates or limits health care provider decision-making relating to the use of clinical laboratory services. Further, the term, "clinical laboratory services" is defined. The bill specifies that this provision does not prohibit prior authorization requirements that the HMO has regarding the provision of clinical laboratory services.

Section 6 provides that this act is effective January 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Implementation of the bill may provide health care providers with a greater number of prescription drugs to meet the unique medical needs of their patients and reduce the administrative burden associated with current step therapy or fail first therapy protocols.

To the extent that current step therapy policies contribute to increased costs from increased inpatient admissions and hospital emergency visits, the bill may serve to reduce those costs.

Medicaid managed care plans, insurers, and HMOs may experience an indeterminate increase in costs associated with changes in the step therapy protocols provided in the bill. These cost increases are likely to pass through to the purchasers of health insurance, such as individuals and employers.

The provisions of the bill would not apply to self-insured health plans since plans are preempted from state regulation under the Employee Retirement Income Security Act of 1974. In Florida, an estimated 60 percent of private-sector enrollees obtain coverage through a self-insured plan.

Government Sector Impact:

Medicaid

The Agency for Health Care Administration indicates that the fiscal impact to Florida Medicaid under the provisions and language of the bill is indeterminate. If the bill is enacted, it may have an operational and fiscal impact on the Florida Medicaid program, as it establishes an enrollee entitlement to a prescription after one use of the fail-first protocol and exempts the provider from seeking an override of the fail-first protocol. It is unclear how the bill applies if the health plans themselves do not have restrictions. This will not allow managed care plans to apply the medical necessity definition or utilization

management criteria for any prescribed treatment subsequent to the first prescription utilized under the fail-first protocol.[24]

Division of State Group Insurance/DMS

According to the DMS, with regard to the fail-first protocol (step-therapy) override process requirement for insurers and HMOs, the bill does not affect the state group insurance prescription drug program, as step-therapy is not currently a provision of the plan design.

Further, the DMS states that the provision in the bill that prohibits HMOs from requiring health care providers to use a clinical decision support system or a laboratory benefits management program, to direct or limit provider's decision-making ability could affect the state group health insurance program. Changes to current medical management procedures that cause an HMO's medical costs to increase would result in higher negotiated premiums for the state-contracted HMOs.[25]

Office of Insurance Regulation

Indeterminate. The OIR did not provide a fiscal impact of implementing the provisions of the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967 and 641.31.

This bill creates the following sections of the Florida Statutes: 627.42392 and 641.394.

IX. Additional Information:

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

CS by Banking and Insurance Committee on January 19, 2016:
The effective date of the bill was changed from July 1, 2016, to January 1, 2017. Further,

[24] Agency for Health Care Administration, *Senate Bill 1084 Fiscal Analysis* (Jan. 13, 2016) (on file with the Senate Committee on Banking and Insurance).
[25] Department of Management Services, *Senate Bill 1084 Fiscal Analysis* (Jan. 14, 2016) (on file with Banking and Insurance Committee).

the bill was revised to apply the provisions relating to step therapy or fail first protocols to individual and group insurance policies and HMO contracts.

B. Amendments:

None.