The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 784
INTRODUCER:	Senator Gaetz
SUBJECT:	Health Care
DATE:	March 3, 2015
REVISED:	

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

I. Summary:

SB 784 creates the "Right Medicine, Right Time Act." The bill establishes the Clinical Practices Review Commission within the Department of Health. The commission will review prior authorization, step therapy, or other protocols, submitted by health maintenance organizations, insurers, or Medicaid managed care plans, that limit access to covered services at the point of service to determine if the limitation is supported by sufficient clinical evidence which proves that the limitation does not inhibit timely diagnosis or effective treatment of the specific illness or condition of the covered patient.

Any coverage limitation imposed by a health maintenance organization (HMO), an insurer, or a Medicaid managed care plan must comply with the procedures for approval of coverage limitations by the commission. If the commission finds that sufficient, clinical evidence exists to support a coverage limitation, the Office of Insurance Regulation (insurers and HMOs) or the Agency for Health Care Administration (Medicaid managed care plans) will approve the coverage limitation. If an insurer, without the approval of the Office of Insurance Regulation, imposes a coverage limitation, the insurer and its chief medical officer are liable for any injuries or damages, as defined in s. 766.202, F.S., and economic damages, as defined in s. 768.81(1)(b), F.S. resulting from the patient's restricted access to services determined medically necessary by the treating physician.

The bill requires a Medicaid managed care plan that establishes a prescribed drug formulary or preferred drug list to provide a broad range of therapeutic options for the treatment of diseases. If feasible, the formulary or preferred drug list must include at least two products in each therapeutic class.

Individual and group health insurance policies and HMO contracts must provide a summary statement identifying any diagnostic or therapeutic procedure that is subject to prior authorization or other coverage limitation as well as prescription drugs that are subject to prior

authorization, step therapy or any coverage limitation. The insurer or HMO is required to post the summary statement on the Internet, which will assist consumers in comparing benefits and limitations of each plan.

II. Present Situation:

Regulation of Insurers and Health Maintenance Organizations

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations, 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 pursuant to part III of ch. 641, F.S.[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]

The Florida Insurance Code requires health insurers and HMOs to provide an outline of coverage or other information describing the benefits, coverages, and limitations of a policy or contract. This may include an outline of coverage describing the principal exclusions and limitations of the policy.[4] Section 641.31(4), F.S., requires each contract, certificate, or member handbook of an HMO to delineate the services for which a subscriber is entitled and any limitations under the contract.

Statewide Medicaid Managed Care

Medicaid is a joint federal and state funded program that provides healthcare for low income Floridians. The Agency for Healthcare Administration (Agency) administers the program. In fiscal year 2013-2014, 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. Most Medicaid recipients who are eligible for the full range of Medicaid benefits are enrolled in an MMA plan. Currently, Medicaid managed care plans must provide all prescription drugs listed on the agency's Medicaid preferred drug list (PDL) for at least the first year of operation.

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 condition or

[1] Section 20.121(3)(a)1., F.S.
[2] Section 641.21(1), F.S.
[3] Section 641.495, F.S.
[4] Section 627.642, F.S.

disease.[5] 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.[6]

The agency maintains coverage and limitations policies for most Medicaid services, which are incorporated by reference into the Florida Administrative Code. Medicaid managed care plans cannot be more restrictive than these policies or the Medicaid state plan (which is approved by the federal Centers for Medicare and Medicaid Services) 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 agency for developing a Medicaid preferred drug list. 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 agency's Medicaid PDL, such that the PDL provides for medically appropriate drug therapies for Medicaid recipients and an array of choices for prescribers within each therapeutic class. The agency also manages the federally-required Medicaid Drug Utilization Board, which meets quarterly and develops and reviews clinical prior authorization criteria, including step-therapy protocols for certain drugs that are not on the agency's Medicaid PDL.

Managed care plans serving Managed Medical Assistance enrollees are required to provide all prescription drugs listed on the agency's Medicaid preferred drug list (PDL) for at least the first year of operation. 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 agency. Section 409.967, F.S., currently requires managed care plans to 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.

State Group Insurance

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 of the Internal Revenue Code.[7] As part of the State Group Insurance Program, the DMS contracts with third party administrators for the self-insured State Employees' PPO Plan and four

[5] Agency for Health Care Administration Bill Analysis, SB 784 (February 13, 2015) (on file with Banking and Insurance Committee).
[6] 42 CFR 438.236(b).
[7] Section 110.123, F.S.

self-insured HMO plans; contracts directly with two fully-insured HMOs; and contracts with a pharmacy benefits manager (PBM) for the State Employees' Prescription Drug Plan.[8] The State Employees' Prescription Drug Plan covers all PPO and HMO plan members (excluding Medicare Advantage Plans offered exclusively to eligible retirees). Summary information about the plans is available on the Internet.[9]

The Division of State Group Insurance indicates that health plan administrators, HMOs and the PBM each have their respective clinical coverage guidelines and utilization management practices to ensure appropriateness of care and to manage plan costs.[10] 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.

Cost Containment Measures Used by Insurers and HMOs

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on the use of certain drugs on their formulary, such as requiring enrollees to obtain prior authorization from their plan before being able to fill a prescription, requiring enrollees to first try 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 of time.

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 preferred drug list (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 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.

[8] Section 110.12315, F.S.
[9] Summary plan descriptions and certificates of coverage for the state group health insurance program are available at http://mybenefits.myflorida.com/health/forms_and_resources/forms_and_publications/health_insurance_forms_and_publications and on the respective vendor websites.
[10] Department of Management Services, SB 784 Analysis (February 26, 2015) (on file with Senate Banking and Insurance Committee).

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. [11] A review of the literature by Brenda Motheral found that there is little good empirical evidence[12], but other studies[13] suggest 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.[14] 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.[15]

Federal regulations for Medicaid and the Children's Health Insurance Program (or CHIP, which, in Florida, is known as Kidcare) require that managed care plans have written policies and procedures for initial and continuing authorization decisions that ensure timely access to care for enrollees with serious and chronic conditions.[16] Under these federal regulations, prior authorization decisions may not exceed 14 calendar days following receipt of the request, with a possible extension up to 14 additional calendar days if requested by the enrollee or provider or there is a need for additional information. For Medicaid, an expedited authorization process is also provided that does not exceed 3 working days with the ability to extend up to 14 calendar days upon enrollee request, or if the managed care plan justifies a need for additional information and the extension is in the enrollee's benefit.[17] Regulations governing the CHIP provide a deferral to any existing state law on the authorization of health services, if applicable.[18]

Recently, the Banking and Insurance Committee staff surveyed insurers regarding their use of prior authorization, step therapy, and P&T Committees. The four companies surveyed have Pharmacy and Therapeutic Committees. Respondents indicated that prior authorization and step therapy could be used for multiple purposes, such as patient safety, expectation of long-term health outcomes, overutilization of a service related to evidence based criteria, and potentially available lower cost solutions with equal health outcomes comparable to higher cost solutions.

Patient Protection and Affordable Care Act (PPACA)

The federal PPACA was signed into law on March 23, 2010.[19] The PPACA imposes many insurance requirements including required benefits, coverage for all individuals and employers,

[11] 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.
[12] Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature, Brenda R. Motheral, *Journal of Managed Care Pharmacy* 17, no. 2 (2011) 143-55.
[13] See fn. 11 at pg. 1780.
[14] See *id*.
[15] See *id*.
[16] See 42 CFR 438.210 (Medicaid) and 42 CFR 495 (Children's Health Insurance Program).
[17] 42 CFR 438.210.
[18] 42 CFR 457.495(d)(2).
[19] P.L. 111-148. On March 30, 2010, PPACA was amended by P.L. 111-152, the Health Care and Education Reconciliation Act of 2010.

rating and underwriting standards, reporting of medical loss ratios and payment of rebates, internal and external appeals of adverse benefit determinations, and other requirements.[20]

Qualifying coverage may be obtained through an employer, the federal or state exchanges created under PPACA, or private individual or group coverage meeting the minimum essential benefits coverage standard. 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 requirements to be deemed a qualified health plan (QHP). If a QHP is not certified, the product may be offered outside the exchange, but individuals purchasing that product would not be eligible for a premium subsidy, which are limited to coverage purchased through the exchange. Insurers seeking initial certification or recertification of qualified health plans (QHPs) for the 2016 enrollment must submit applications to Centers for Medicare and Medicaid Services (CMS) by May 15, 2015. The final deadline for state approval and for QHPs to send final data to CMS is August 25, 2015.

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 list, and the drug exception process.[21]

Prescription Drug Coverage.[22] The current drug coverage policy of HHS is based on insurers including in their formulary drug lists 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 EHB benchmark plan. Under the final rule, issuers must also use a pharmacy and therapeutic (P&T) committee system, which will 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. Issuers will use the P&T committee process, starting in 2017, and must also satisfy the current USP drug count standard.

Formulary Drug List. The regulations clarify that a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure and any restrictions on the manner in which a drug can be obtained, in a manner that is

[20] 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.).
[21] 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 March 3, 2015).
[22] Section 1302 of PPACA provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB. The law directs that EHBs be equal in scope to the benefits covered by a typical employer plan and that they cover at least 10 general categories including prescription drugs.

easily accessible to plan enrollees, prospective enrollees, the state, the marketplace, HHS, and the general public. Additionally, issuers must also make this information available in a standard machine-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Drug Exceptions Process. The HHS current regulations require that issuers have processes through which an enrollee can request and gain access to a drug not on the formulary. In the final rule, HHS established more detailed procedures for the standard review process, and a requirement that issuers have a process in place under which an enrollee can request an independent external review if the health plan denies an initial request made on a standard or expedited basis. HHS also clarified that cost sharing for drugs obtained through the exceptions process must count toward the annual limitation on cost sharing for health plans subject to the EHB requirement.

Summary of Benefits and Coverage

Section 2715 of the PHS Act, directs HHS, and the Department of Treasury to develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage in compiling and providing a summary of benefits and coverage (SBC) that ‘‘accurately describes the benefits and coverage under the applicable plan or coverage.” On December 30, 2014, HHS issued proposed rules relating to the summary of benefits and coverage that would require issuers to make available on an Internet web address a copy of the actual individual coverage policy or group certificate of coverage.[23] The SBC must include other information, such as:

- A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance.
- The exceptions, reductions, and limitations of the coverage.
- For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage.

III. Effect of Proposed Changes:

Section 1 creates the “Right Medicine, Right Time Act.”

Section 2 creates s. 402.90, F.S., and establishes the Clinical Practices Review Commission (commission), which would be housed for administrative purposes within the Division of Medical Quality Assurance of the Department of Health. The commission would consist of the following seven appointed members, subject to confirmation by the Senate:

- Five physicians who are currently practicing medicine in Florida and have clinical expertise as specified in the bill.
- One individual, appointed by the Governor, with a doctorate in pharmacology or pharmacy and meeting specified experience and credentials.
- One member, appointed by the Governor, with expertise in the analysis of clinical research and meeting other requirements.

The powers and duties of the commission include:

[23] *See* Summary of Benefits and Coverage and Uniform Glossary, 79 Fed. Reg. 78,607-78611, (December 30, 2014).

- Development and implementation of policies and procedures for the review of prior authorization, step therapy, or other protocols that limit, at the point of service, access to covered services, including diagnostic procedures, pharmaceutical services, and other therapeutic interventions.
- Development of any operational policies and procedures that would facilitate the work of the commission, including the establishment of bylaws, the election of a chair, and other administrative procedures.
- Determination as to the sufficiency of clinical evidence submitted in support of any proposed coverage limitation.
- Preparation of reports and recommendations that document the proceedings of the commission and identify necessary resources or legislative action.

The bill provides that commission members and specified commission staff are subject to part III, of chapter 112, F.S., including the Code of Ethics for Public Officers and reporting of financial interests pursuant to s. 112.3145, F.S. For purposes of part III of ch. 112, F.S., the executive director, senior managers, commission members are considered public officers or employees and the commission is considered their agency. Each commission member is prohibited from voting on any measure that would inure to his or her special private gain or loss. Similar prohibitions apply to voting on any measure that would benefit any principal, parent organization or subsidiary of a corporate principal by which he or she is retained or to a relative or business associate of the public officer. Senior managers and commission members are required to file the disclosure requirements with the Commission on Ethics. An employee or commission is prohibited from accepting any gift or expenditure from a person which has a contractual relationship with the commission or which is under consideration for a contract. An employee or commission member that fails to comply with these requirements is subject to the penalties provided under ss. 112.317 and 112.3173, F.S.

Subject to an appropriation, a commission member may receive compensation, per diem and travel expenses as provided in s. 112.061, F.S.

Section 3 amends s. 409.967, F.S., and establishes requirements for prescribed drug formularies or preferred drug lists of Medicaid managed care plans. If a Medicaid managed care plan establishes a prescribed drug formulary or preferred drug list, the plan must provide a broad range of therapeutic options for the treatment of disease states, which are consistent with the general needs of the outpatient population. If feasible, the formulary or preferred drug list must include at least two products in each therapeutic class. The section also requires such plans to comply with the procedures for approval of coverage limitations by the commission and the agency as provided pursuant to ss. 627.6051 and 641.31(44), F.S.

Section 4 creates s. 627.6051, F.S., and requires that any coverage limitation imposed by an insurer at the point of services must be supported by sufficient clinical evidence providing that the limitation does not inhibit timely diagnosis or effective treatment of the specific illness or condition for the covered patient. The bill defines the term, "sufficient clinical evidence," to mean:

- A body of research consisting of well-controlled studies conducted by independent researchers and published in peer reviewed journals or comparable publications, which

consistently support the treatment protocol or other coverage limitation as a best practice for the specific diagnosis or combination of presenting complaints.
- Results of a multivariate predictive model, which indicate that the probability of achieving desired outcomes is not negatively altered or delayed by adherence to the proposed protocol.

The commission is required to determine whether sufficient clinical evidence exists for a proposed coverage limitation imposed by an insurer at the point of service. If the commission determines that sufficient clinical evidence exists to support a coverage limitation, the OFR must approve the coverage limitation.

If an insurer, without the approval of the OIR, imposes a coverage limitation, the insurer and its chief medical officer are liable for any injuries or damages, as defined in s. 766.202, F.S., and economic damages, as defined in s. 768.81(1)(b), F.S., resulting from the patient's restricted access to services determined medically necessary by the treating physician.
Section 768.81(1)(b), F.S., defines the term, "economic damages" to mean past lost income and future lost income reduced to present value; medical and funeral expenses; lost support and services; replacement value of lost personal property; loss of appraised fair market value of real property; costs of construction repairs, including labor, overhead, and profit; and any other economic loss that would not have occurred but for the injury giving rise to the cause of action.

Section 766.202, F.S., defines the term, "economic damages," to mean financial losses that would not have occurred but for the injury giving rise to the cause of action, including, but not limited to, past and future medical expenses and 80 percent of wage loss and loss of earning capacity to the extent the claimant is entitled to recover such damages under general law, including the Wrongful Death Act. "Noneconomic damages" is defined to mean nonfinancial losses that would not have occurred but for the injury giving rise to the cause of action, including pain and suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of capacity for enjoyment of life, and other nonfinancial losses to the extent the claimant is entitled to recover such damages under general law, including the Wrongful Death Act.

Sections 5, 7, and 8 amend ss. 627.642, 627.662, and 627.6699, F.S., to require individual and group health insurance policies to provide a summary statement identifying any diagnostic or therapeutic procedure that is subject to prior authorization or other coverage limitation as well as prescription drugs that are subject to prior authorization, step therapy or any coverage limitation. The insurer is required to post the summary statement on the Internet, which will assist consumers in comparing benefits and limitations of each plan.

Section 6 amends s. 627.651, F.S., to provide a technical, conforming cross reference.

Section 9 amends s. 641.31(44), F.S., to require HMO contracts to provide a summary statement identifying any diagnostic or therapeutic procedure that is subject to prior authorization or other coverage limitation as well as prescription drugs that are subject to prior authorization, step therapy or any coverage limitation. The HMO is required to post the summary statement on the Internet, which will assist consumers in comparing benefits and limitations of each plan.
The section also provides that HMOs are prohibited from establishing prior authorization procedures, step therapy requirements, treatment protocols, or other utilization management procedures that restrict access to covered services unless expressly authorized. Any coverage

limitation imposed by a HMO at the point of service must be supported by sufficient clinical evidence as defined in s. 627.6051, F.S., which demonstrates that the limitation does not inhibit timely diagnosis or optimal treatment of the specific illness or condition of the covered patient.

Section 10 provides that the act will take effect October 1, 2015.

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 drugs and treatments to meet the unique medical needs of their patients in a timelier manner.

Health care providers may experience less administrative costs associated with prior authorization protocols and formularies. One study estimated that prior authorization requests consumed about 20 hours a week per medical practice: 1 hour of the doctor's time, nearly 6 hours of clerical time, plus 13 hours of nurses' time.[24]

The bill provides an October 1, 2015, effective date. According to the OIR, insurers are required to file their qualified health plan applications for new and old plans to be offered on the exchange by May 15, 2015, and such applications must be finalized by August 25, 2015.

Insurers, managed care organizations, and health maintenance organizations may experience an indeterminate increase in costs to cover prescription drugs and other

[24] Theodore Karrison and Wendy Levinson, What Does It Cost Physician Practices To Interact With Health Insurance Plans? published online May 14, 2009, Health Affairs, 28, no.4 (2009):w533-w543 accessed at http://content.healthaffairs.org/content/28/4/w533.full (last visited March 2, 2015).

coverage limitations if the commission does not find sufficient clinical evidence to support coverage limitations imposed by the respective entity. Typically, step-therapy is applied to a certain drug class with the goal of encouraging generic drug use and decreasing costs. Those cost increases are likely to pass through to the purchasers of health insurance coverage, such as individuals and employers.

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

The posting of summary statements regarding coverage limitation by insurers and health maintenance organizations will provide greater transparency of information for consumers and health care providers.

The provisions of the bill would not apply to self-insured health plans since these plans are preempted from state regulation under the Employee Retirement Income Security Act of 1974. In Florida, approximately 60 percent of private-sector enrollees are enrolled in self-insured plans.

C. Government Sector Impact:

Department of Health

The cost to establish and operate the Clinical Practices Review Commission is indeterminate at this time.

Impact on Medicaid

The fiscal impact to Medicaid is indeterminate. The bill requires the Clinical Practices Review Commission to determine whether sufficient clinical evidence exists for a proposed coverage limitation imposed by the insurer at the point of service. This provision of the bill will have an operational and fiscal impact on the Medicaid program. The bill does not limit the types of services or coverage limitations that would be subject to this requirement. Therefore, managed care plans would have to obtain approval from the commission for any limitation placed on a covered service – this could become administratively burdensome and duplicate processes that the plan has already established to monitor their utilization management program for clinical appropriateness. The Agency for Health Care Administration would also have to amend its contracts with the managed care plans to include this requirement.

To the extent that the commission disagrees with a coverage limitation, the managed care plan may incur additional expenses for providing services that are not medically necessary or for which an equally effective and less costly alternative treatment exists that can meet the needs of the enrollee.

SB 784 requires managed care plans serving MMA enrollees to provide a broad range of therapeutic options on their prescribed drug formulary or preferred drug list. Since

managed care plans have not established their own plan-specific formulary or preferred drug list, this change would not result in a fiscal or operational impact to the Medicaid program, at this time.

According to the Agency for Health Care Administration, the contracts with the Medicaid managed care plans have several quality and utilization management provisions to ensure enrollees receive medically necessary services in a timely manner. Requiring the commission to review all coverage limitations proposed by Medicaid managed care plans may also duplicate processes that the plans have already established to monitor their utilization management programs for clinical appropriateness.

Division of State Group Insurance

This bill would have a negative indeterminate fiscal impact to the State Employees' Health Insurance Trust Fund. Changes to current medical management procedures that cause an HMO's medical costs to increase could result in higher negotiated premiums for the state-contracted HMOs.

VI. Technical Deficiencies:

None.

VII. Related Issues:

If the bill becomes law, the Agency for Health Care Admiration states that it presents a potential conflict with Medicaid law.[25] Pursuant to 42 CFR 431.10, each state must "specify a single State agency established or designated to administer or supervise the administration of the plan." "The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State." Pursuant to s. 409.901, F.S., the agency is designated as the single state agency. As such, the agency is the final authority as to coverage and limitations related to Medicaid. Having other commissions or agencies determine coverage and limitations at the point of service would be contrary to Medicaid law and could possibly lead to a determination that is contrary to governing state and/or federal Medicaid law, the Medicaid managed care contract, the Medicaid State Plan, any governing federal Medicaid waivers. Thus, coverage limitations implemented by AHCA should be exempt from these requirements.

Section 627.6051(1), F.S., places liability on an insurer and its chief medical officer who uses a non-approved limitation. Currently, the state group insurance program is protected by sovereign immunity because it is a program established by the State of Florida. Section 627.6051(1) does not specify whether the Legislature is waiving the program's sovereign immunity.

[25] Agency for Health Care Administration Bill Analysis (February 13, 2015) (on file with Banking and Insurance Committee).

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967, 627.642, 627.651, 627.662, 627.6699, and 641.31.

This bill creates the following sections of the Florida Statutes: 402.90 and 627.6051.

IX. Additional Information:

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

None.

B. Amendments:

None.