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 530
INTRODUCER:	Senator Steube
SUBJECT:	Health Insurance
DATE:	March 24, 2017
REVISED:	

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

I. Summary:

SB 530 revises provisions of the Insurance Code relating to prior authorization and step therapy or fail first protocols. The bill creates an expedited, standard process for the approval or denial of prior authorizations and protocol exceptions, which provides greater transparency for consumers and providers regarding policies and procedures. Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a health care service under the plan. 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. However, 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. The bill provides the following changes:

- Requires a health insurer, pharmacy benefit manager (PBM) or utilization review entity (URE) to authorize or deny a prior authorization request or a protocol exception request or appeal of a denial in nonurgent circumstances and notify the insured and the patient's health care provider within 3 business days after obtaining all necessary information to make the determination. In urgent circumstances, such approval or denial and notification must be made within 24 hours.
- Provides greater transparency for consumers by requiring health insurers, PBMs and UREs to provide access to any current prior authorization requirements, restrictions, and forms on its website and in written or electronic form upon request. If a health insurer, PBM, or URE intends to amend or implement a new prior authorization requirement or restriction, such entity must update the website 60 days prior to the implementation of the new requirement or restriction. Written notice of the change must be provided to all insureds using the affected service and to all contract providers who provide the affected services at least 60 days before the implementation date.

- Provides that a protocol exception must be granted if the preceding prescription drug will likely cause an adverse reaction or harm, is expected to be ineffective, or is not in the best interest of the patient.
- Requires that if the insurer denies the protocol exception request or denial, the insurer must provide to the insured and treating provider notice of the denial, including a detailed written explanation of the reason for the denial.

The impact of the bill on the Medicaid program is indeterminate. The State Group Insurance program indicates that the two fully-insured HMOs would incur an indeterminate negative impact. The provisions of the bill would not have a fiscal impact on the state's self-funded insurance plans.

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]

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] Further, each contract, certificate, or member handbook of an HMO must delineate the services for which a subscriber is entitled and any limitations under the contract.[5]

Section 627.4234, F.S., requires a health insurance policy or health care services plan, which provides medical, hospital, or surgical expense coverage delivered or issued for delivery in this state to contain one or more of the following procedures or provisions to contain health insurance costs or cost increases:

- Coinsurance.
- Deductible amounts.
- Utilization review.
- Audits of provider bills to verify that services and supplies billed were furnished and that proper charges were made.
- Scheduled benefits.
- Benefits for preadmission testing.

[1] Section 20.121(3)(a), F.S.
[2] Section 641.21(1), F.S.
[3] Section 641.495, F.S.
[4] Section 627.642, F.S.
[5] Section 641.31(4), F.S.

- Any lawful measure or combination of measures for which the insurer provides to the office information demonstrating that the measure or combination of measures is reasonably expected to have an effect toward containing health insurance costs or cost increases.

Pursuant to s. 627.42392, F.S., any health insurer (health insurer, HMO, Medicaid managed care plan) or pharmacy benefit manager that does not use an online prior authorization form must use a standardized prior authorization form the Financial Services Commission adopts by rule to obtain a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form must include all clinical documentation necessary for the health insurer to make a decision.

Florida's Statewide Medicaid Managed Care

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, the Agency for Health Care Administration (agency) oversees the Medicaid program.[6] The Statewide Medicaid Managed Care (SMMC) program is comprised of the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) managed care program. The agency contracts with managed care plans to provide services to eligible recipients.[7]

Managed Care Covered Services

The benefit package offered by the MMA plans is comprehensive and covers all Medicaid state plan benefits (with very limited exceptions). This includes all medically necessary services for children. Most Florida Medicaid recipients who are eligible for the full array of Florida Medicaid benefits are enrolled in an MMA plan. The agency maintains coverage policies for most Florida Medicaid services, which are incorporated by reference into ch. 59G-4, F.A.C. Florida 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) in providing services to their enrollees.

Section 409.91195, F.S., establishes the Pharmaceutical and Therapeutics (P&T) committee within the agency 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 agency's 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 agency 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 Medicaid PDL.

[6] Part III of ch. 409, F.S., governs the Medicaid program.
[7] A managed care plan that is eligible to provide services under the SMMC program must have a contract with the agency to provide services under the Medicaid program; be a health insurer, an exclusive provider organization or a HMO authorized under ch. 624, 627, or 641, F.S., respectively, or a provider service network authorized under s. 409.912(2), F.S., or an accountable care organization authorized under federal law. (s. 409.962, F.S.)

Florida Medicaid managed care plans serving MMA enrollees are required to provide all prescription drugs listed on the agency's PDL and otherwise covered by Medicaid. [8] As such, the Florida Medicaid managed care plans have not implemented their own plan-specific formulary or PDL. The Florida Medicaid managed care plan's prior authorization criteria/protocols related to prescribed drugs cannot be more restrictive than the criteria established by the agency.

Prior Authorization Requirements

Florida Medicaid managed care plans may implement service authorization and utilization management requirements for the services they provide under the SMMC program. However, Florida 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 providers who have the appropriate clinical expertise in treating the enrollee's condition. The Florida Medicaid 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.[9]

Florida Medicaid managed care plans must establish and maintain a utilization management system to monitor utilization of services, including an automated service authorization system for denials, service limitations and reductions of authorization. Section 627.42392, F.S., relating to prior authorization, requires the use of a standard prior authorization form by health insurers, which is defined to include managed care plans and HMOs. A health insurer that does not provide an electronic prior authorization process for use by its providers, is required to use the prior authorization form approved by the Financial Services Commission for authorization of procedures, treatments, or prescription drugs. Currently, Medicaid managed care plans are required by contract to have electronic authorization processes, therefore they are exempt from this provision.

The SMMC contract requires managed care plans to authorize or deny a standard request for prior authorization for services other than prescribed drugs within 7 days, and authorize or deny an expedited request within 48 hours of receiving the request. Within 24 hours after receipt of a request, a managed care plan must respond to a request for prior authorization. The timeframe for standard authorization decisions can be extended up to 7 additional days if the enrollee or the provider requests an extension or the managed care plan justifies the need for additional information and describes how the extension is in the enrollee's interest.

Enrollee Materials and Services

Managed care plans are contractually required to notify enrollees via the enrollee handbook of any procedures for obtaining required services and authorization requirements, including any

[8] See Agency for Health Care Administration Pharmacy Policy available at http://ahca.myflorida.com/Medicaid/Policy_and_Quality/Policy/pharmacy_policy/index.shtml (last visited Mar. 19, 2017).
[9] These guidelines are consistent with requirements found in federal and state regulations (See 42 CFR s. 438.236(b)). All service authorization decisions made by the managed care plans must be consistent with the State's Medicaid medical necessity definition (ch. 59G-1.010, F.A.C).

services available without prior authorization. All enrollee communications, including written materials, spoken scripts, and websites, must be at or near the fourth grade reading level. Managed care plans are required by contract to issue a provider handbook to all providers that includes prior authorization and referral procedures, including required forms. Managed care plans are required to keep all provider handbooks and bulletins up to date and in compliance with state and federal laws. The managed care plans must notify its enrollees in writing of any changes to covered services or service authorization protocols at least 30 days in advance of the change.

The managed care plan must send a written notice of adverse benefit determination to the enrollee to inform the enrollee about a decision to deny, reduce, suspend, or terminate a requested service and provide directions on how the enrollee may ask for a plan appeal to dispute the managed care plan's adverse benefit determination. The enrollee has 60 days after the plan's adverse benefit determination to ask for a plan appeal. For decisions that are appealed, the managed care plan must have a second health care professional who was neither involved in any previous level of review or decision-making, nor a subordinate of any such individual. The managed care plan then has 30 days from the date of the enrollee's request to make a final decision. The managed care plan has 72 hours to respond to the enrollee or his or her authorized representative's request for an expedited plan appeal. The enrollee must complete the plan appeal process before asking for a Medicaid fair hearing.

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 s. 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.

Contractually, health plans and contracted third party administrators are required to review urgent or emergency UR prior authorization requests within 24 hours of receipt and within 14 calendar days of initial receipt for routine requests. Current industry standards for a utilization review change notices to plan participants/enrollees is 30 days.

Federal Patient Protection and Affordable Care Act

Health Insurance Reforms

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[10] The PPACA requires 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 also mandates required essential health

[10] The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.

benefits,[11] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.

The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.[12] To be certified as a QHP, the insurer must also submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.[13] The federal deadline for insurers and HMOs to submit 2018 rates and forms to the Florida Office of Insurance Regulation is May 3, 2017.[14,15]

Prescription Drug Coverage

For purposes of complying with PPACA's EHBs for prescription drugs, plans 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 EHB benchmark plan. Issuers must have a Pharmacy and Therapeutics Committee 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.

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 an exception process to request an expedited review.[16] The PPACA also requires plans to implement an internal appeals and independent external review process if an enrollee is denied coverage of a drug on the formulary.[17]

Plans are required to 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 way 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.[18] Restrictions include prior authorization, step therapy, quantity limits and access restrictions. The Centers for Medicare and Medicaid Services collects federally-facilitated Marketplace QHPs' formulary drug list websites as part of the QHP application and makes formulary drug list links provided by plans available to consumers on

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[11] 42 U.S.C. s.18022.
[12] See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Feb. 13, 2017) for Florida's benchmark plan.
[13] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last viewed Feb. 13, 2017).
[14] Office of Insurance Regulation, *Guidance to Insurers*, available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last viewed Mar. 19, 2017).
[15] President Trump, Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and (Jan. 20, 2017). President Trump issued an executive order indicating that it is the intent of his administration to seek the prompt repeal of PPACA. (last viewed: Mar. 19, 2017).
[16] 45 C.F.R. s. 156.122(c).
[17] 45 C.F.R. s. 147.136.
[18] 45 C.F.R. s. 156.122(d).

HealthCare.gov.[19] A formulary drug list is easily accessible when it can be viewed on the plan's public website through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and if an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.[20]

Cost Containment Measures Used by Insurers and HMOs

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 medical treatments or 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 use a step therapy protocol, which requires the 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. Generally, 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.[21] A review of the literature by Brenda Motheral found that there is little good empirical evidence,[22] but other studies[23] 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

[19] According to CMS, this formulary drug list website link should be the same direct formulary drug list link for obtaining information on prescription drug coverage in the Summary of Benefits Coverage, in accordance with 45 CFR s. 147.200(a)(2).
[20]See CMS 2018 Letter to Issuers available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf (last viewed Mar. 20, 2017).
[21] 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.
[22] Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature, Brenda R. Motheral, *Journal of Managed Care Pharmacy* 17, no. 2 (2011) 143-55.
[23] *Supra* note 15, at 1780.

utilization costs over the long run because of increased inpatient admissions and emergency department visits. 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.[24]

III. Effect of Proposed Changes:

Section 1 revises s. 627.42392, F.S., relating to prior authorization by health insurers (which includes health insurers as defined in s. 624.603, F.S., Medicaid managed care plans, and HMOs) or a pharmacy benefit managers on behalf of a health insurer. The section provides definitions of the terms, "urgent health care service" and "utilization review entity." An "urgent health care service" means a health care service that is subject to the period for making a nonexpedited prior authorization, such period without the service, in the opinion of a physician with knowledge of the patient's medical condition, could:

- Seriously jeopardize the life or health of the patient;
- Seriously jeopardize the patient's ability to regain maximum function; or
- Subject the patient to severe pain that cannot be managed adequately.

The term, "utilization review entity," means an entity that performs prior authorization for a health insurer.

The section requires a utilization review entity or health insurer to make any current prior authorization requirements, restrictions, and forms readily accessible on its website and in written or electronic form upon request for beneficiaries, health care providers, and the public. The requirements must be described in clear and easily understandable language. Further, the bill requires any clinical criteria to be described in language easily understandable by a provider. If a utilization review entity or health insurer intends to amend or implement new prior authorization requirements or restrictions, the utilization review entity or health insurer must:

- Ensure that the new or amended requirements or restrictions have been updated on the respective website at least 60 days before implementation of the restriction or requirement. This requirement does not apply to expansion of coverage.
- Provide notice to beneficiaries currently using those services and all contracted health care physicians who provide the affected services at least 60 days before implementation of the restriction.

Health insurers must approve or deny prior authorization requests in urgent and nonurgent circumstances within 24 hours and 3 business days, respectively, after obtaining all necessary information to make the determination. Notice must be given to the patient and the patient's treating provider.

Sections 2 creates s. 627.42393, F.S., relating to step therapy or fail first protocols. The term, "fail first protocol,"means a protocol that specifies the order in which certain prescription drugs or medical treatments must be used to treat an insured's condition.

[24] I*d.*

The term, "plan," means an authorized insurer offering health insurance as defined in s. 624.603, F.S., a Medicaid managed care plan, or a HMO. The section defines the term, "preceding prescription drug or medical treatment," to mean a prescription drug or medical treatment that according to a fail first protocol, must be used first to treat an insured's condition and then must be determined, as a result of such treatment, to be inappropriate to treat the insured's condition before a succeeding treatment with another prescription drug or medical treatment is covered.

The section defines the term, "protocol exception," to mean a plan's determination, based on a review of a request for the determination and any supporting documentation, that:

- A fail first protocol is not medically appropriate or indicated for treatment of a particular insured's condition; and
- The plan will not require the insured's use of a preceding prescription drug or medical treatment under the fail first protocol and will provide immediate coverage for another prescription drug or medical treatment that is prescribed or recommended for the insured.

A plan is required to publish on the plan's website and provide in writing to an insured a process for requesting a protocol exception. The procedure must include the following provisions:

- A description of the manner in which an insured may request a protocol exception.
- The plan must make a determination concerning a protocol exception request or an appeal of a denial of a protocol exception request within 24 hours after receiving the request or appeal in an urgent care situation; or within 3 business days after receiving the request or appeal in a nonurgent care situation.
- A protocol exception will be granted if any of the following applies:
    - A preceding prescription drug or medical treatment is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.
    - A preceding prescription drug is expected to be ineffective based on both the known clinical characteristics of the insured and the known characteristics of the preceding prescription drug or medical treatment as found in sound clinical evidence.
    - The insured previously received a preceding prescription drug or another prescription drug that is in the same pharmacologic class or that has the same mechanism of action as a preceding prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
    - Based on clinical appropriateness, a preceding prescription drug or medical treatment is not in the best interest of the insured because the insured's use of the preceding prescription drug or medical treatment is expected to cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care; worsen a comorbid condition of the insured; or decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.
- When a protocol exception is granted, the plan must notify the insured and the insured's health care provider of the authorization for coverage of the prescription drug or medical treatment that is the subject of the protocol exception.
- If a protocol exception request or an appeal of a denied protocol exception request results in a denial of the protocol exception, the plan must provide to the insured and treating health care provider notice of the denial, including a detailed written explanation of the reason for the denial and the clinical rationale that supports the denial.

- The plan may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

Section 3 provides that this act is effective July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Constitutional Issues:

The bill revises provisions affecting persons who have or may have a contract with an insurer or HMO. In *Pomponio v. Claridge of Pompano Condominium, Inc*.,[25] the Florida Supreme court stated that some degree of flexibility has developed over the last century in interpreting the contract clause in order to ameliorate the harshness of the original rigid application used by the United States Supreme Court. The Florida Supreme Court invalidated a statute, as an unconstitutional impairment of contract, which required the deposit of rent into a court registry during litigation involving obligations under a contract lease. The court set forth several factors to be considered in balancing whether a state law has in fact operated as a substantial impairment of a contractual relationship, stating "[t]he severity of the impairment measures the height of the hurdle the state legislation must clear."

The court stated that if there is minimal alteration of contractual obligations, the inquiry may end at its first stage. Severe impairment pushes the inquiry into a careful examination of the nature and purpose of the state legislation. The factors to be considered are whether:

- The law was enacted to deal with a broad, generalized economic or social problem;
- The law operates in an area that was already subject to state regulation at the time the contract was entered into; and
- The effect on the contractual relationships is temporary or whether it is severe, permanent, immediate, and retroactive.

In *United States Fidelity & Guaranty Co. v. Department of Insurance,*[26] the Florida Supreme Court followed *Pomponio* and said that the method requires a balancing of a

[25] *Pompano v. Claridge of Pompanio Condominium, Inc.*, 378 So.2d 774 (Fla. 1979).
[26] *United States Fidelity & Guaranty Co. v. Department of Insurance*, 453 So.2d 1355 (Fla. 1984).

person's interest to not have his or her contracts impaired, with the state's interest in exercising its legitimate police power. The court adopted the method used by the U.S. Supreme Court, in which the threshold inquiry is "whether the state law has, in fact, operated as a substantial impairment of a contractual relationship." The severity of the impairment increases the level of scrutiny.

Relevant to the extent of the impairment is whether the industry, the complaining party had entered, had been regulated in the past because if the party was already subject to regulation when the contract was entered, then it is understood that it would be subject to further legislation upon the same topic. If the state regulation constitutes a substantial impairment, the state must have a significant and legitimate public purpose and any adjustment of the rights and responsibilities of the contracting parties must be appropriate to the public purpose justifying the legislation.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Implementation of the bill may give health care providers greater flexibility in prescribing medications to meet the unique medical needs of their patients and reduce the administrative burden associated with the prior authorization process and the current step therapy or fail first therapy protocols.

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.

C. Government Sector Impact:

Medicaid[27]

According to the agency, Senate Bill 530 will have an indeterminate fiscal impact on the agency. The bill will require the agency to amend the SMMC contracts to modify the prior authorization requirements and the utilization review timeframes. The operational impact of amending the contract will use current agency resources to complete. The bill will significantly affect the business (staffing, systems, etc.) and clinical operations of the

[27] Agency for Health Care Administration, *Senate Bill 530 Analysis* (Feb. 22, 2017) (on file with the Senate Committee on Banking and Insurance).

Medicaid managed care plans. The bill requires the plans to shorten the time to review authorizations, which will increase the administrative costs.

The agency notes that the situations specified in the bill, for which a plan would be required to authorize a request for a "protocol exception," should already be contemplated in the plans' clinical/evidence based authorization criteria under the SMMC program and are factors addressed in the application of the State's Medicaid medical necessity definition. All Medicaid managed care plans must use the State's Medicaid medical necessity definition in their approval and denial of services. As such, it is unclear of the benefit achieved from applying the requirements related to the "protocol exception" to managed care plans furnishing services under the SMMC program, other than to add administrative requirements on the plans in an effort to expedite authorization decisions. The timely response standards for protocol exceptions will require the plan to increase the authorization staff and will result in an increase in administrative expenses. These increased costs will need to be reflected in the SMMC capitation rates as administrative expenses.

Division of State Group Insurance/DMS[28]

The fiscal impact of the bill is unknown. However, the division's fully insured HMO vendors, Capital Health Plan (CHP) and Florida Health Care Plans (FHCP), would be negatively impacted by the bill. The initial estimated impact for CHP would be $450,000.00 annually. FHCP was unable to provide a monetized impact estimate. The provisions of the bill would not affect the state's self-funded insurance plans.

The requirement of a 60-day notice for utilization review changes may prevent timely changes when external or internal factors facilitate an urgent need for the change. The 60-day notice requirement could discourage utilization review changes all together, many of which are made to maintain or increase quality. Other changes are made to assist in the elimination of fraud, abuse and overuse of certain prescription drugs and medical treatments. The division's contracted pharmacy benefits manager, CVS / Caremark, raised specific concerns with the language on lines 186-194. Based upon their review, this section could be interpreted to broadly indicate that any fail-first protocol should be avoided.

Office of Insurance Regulation

None.[29]

VI. Technical Deficiencies:

Terms

[28] Department of Management Services, *Senate Bill 530 Analysis* (Mar. 23, 2017) (on file with Senate Committee on Banking and Insurance).
[29] Office of Insurance Regulation, *Senate Bill 530 Analysis* (Feb. 2, 2017) (on file with the Senate Committee on Banking and Insurance).

In existing s. 627.42392, F.S., (section 1 of the bill) and newly created s. 627.42393, F.S., (section 2 of the bill) the definition of health insurer

> "includes an authorized insurer offering health insurance, as defined in s. 624.403, F.S., which provides it is insurance of human beings against bodily injury, disablement, or death by accident or accidental means, or the expense thereof, or against disablement or expense resulting from sickness, and every insurance appertaining thereto. Health insurance does not include workers' compensation coverages, except as provided in s. 624.406(4)."

This broad definition would include not only major medical health insurance coverage but also supplemental policies and excepted benefit policies. Supplemental policies and excepted benefit policies generally provide a fixed payment amount upon the occurrence of a certain event and may not be applicable to the bill.

The provisions of the bill apply to health insurers, pharmacy benefit managers, and utilization review entities. The OIR regulates health insurers, however, PBMs and utilization review entities are not licensed or regulated by the OIR. It is unclear whether the health insurer is responsible for the actions of the PBM or URE. Thus, it may be difficult to enforce the provisions of this bill against any health insurer that uses a PBM or URE since these entities are not regulated.

Notice of Prior Authorization Changes

The bill requires health insurers and UREs to provide 60 days' prior notice to insureds and physicians when a health insurer or URE wants to change a prior authorization treatment. However, the bill does not allow for exceptions in circumstances where a drug or procedure is found to be hazardous or could result in harm to an insured.

VII. Related Issues:

Effective Date

According to the OIR, the filing submission deadline for PPACA-compliant form and rate filings in the individual and small group market is May 3, 2017. This deadline is applicable for products sold on and off the exchange. However, the effective date of the bill is July 1, 2017. Many plans operate on a calendar year basis.

According to the agency, given the magnitude of the changes proposed in the bill (including system changes, staffing changes, etc.), it is unlikely that the Medicaid managed care plans would be able to implement such changes by July 1, 2017. Further, since it is projected that these changes will affect the capitation rate setting process, the agency would need time to work with its actuaries to adjust the rates. An implementation timeframe of October 1, 2017, would align with the adoption of new capitation rates each year under the SMMC program and provide the plans with more time to implement any necessary operational changes. It also provides the agency with the time needed to modify and execute revised SMMC contracts to reflect the proposed changes.

VIII. Statutes Affected:

This bill substantially amends section 627.4292 of the Florida Statutes.

This bill creates section 627.4293 of the Florida Statutes.

IX. Additional Information:

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

None.