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 98
INTRODUCER:	Senator Steube
SUBJECT:	Health Insurer Authorization
DATE:	November 6, 2017
REVISED:	11/07/17

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Favorable**
2.			JU	
3.			RC	

I. Summary:

SB 98 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 the policies and procedures of health insurers.

Under a prior authorization process, 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 medical treatment or prescription drugs coverage require an insured or enrollee to try a certain drug or treatment before receiving coverage for another drug or medical treatment. However, timely access to appropriate health care can be critical for individuals who have chronic conditions that may cause death, disability, or serious discomfort.

The bill:

- Requires a health insurer (which means a health insurer, health maintenance organization, or Medicaid managed care plan), or pharmacy benefit manager (PBM) on behalf of a health insurer to authorize or deny a prior authorization request or a protocol exception request or appeal of a denial in nonurgent care situation within 72 hours after receipt of a completed prior authorization form or protocol exception request. In urgent circumstances, a health insurer must authorize or deny a request within 24 hours.
- Provides greater transparency for consumers by requiring health insurers or PBMs to provide public access to current prior authorization requirements, restrictions, and forms on their websites and, upon request, in written or electronic form. If a health insurer or PBM intends to amend or implement a new prior authorization requirement or restriction, the entity must update the website 60 days before the effective date of the new requirement or restriction. Notification of the change must be provided to all insureds or enrollees using the affected service and to all contract providers who provide the affected services at least 60 days before the effective date.

- Requires a health insurer to grant a protocol exception request under certain conditions.
- Provides that if the health insurer authorizes the protocol exception request, the health insurer must specify the approved medical procedure, course of treatment, or prescription drug benefits.
- Requires that if the health insurer denies the protocol exception request, the health insurer must provide specified information, including procedures on appealing a denial.

The bill will have an operational and fiscal impact on the Florida Medicaid program, but the impact to Medicaid is indeterminate. The Agency for Health Care Administration will need to amend the Statewide Medicaid Managed Care contracts to comply with the revised statute, which will affect the business and clinical operations of the Medicaid managed care plans. The bill will likely increase Medicaid costs as the health plans will likely have to deploy additional staffing resources to respond to the prior authorization override inquiries and expedited timeframes as required in the bill. The additional staffing resources will need to be accounted for in the administrative expenses included in the capitation rates, but this cannot be determined thus making the fiscal impact to Florida Medicaid indeterminate.

The State Group Insurance program indicates that the bill would have a fiscal impact on the program. The fully insured health maintenance organization (HMO) vendor, Capital Health Plan (CHP), states that the bill would negatively affect it, specifically; the initial estimated fiscal impact for CHP would be $256,000 annually, based upon the need to employ an additional four medical staff and three support staff employees. The pharmacy benefit, CVS Caremark, indicated that the bill would adversely impact it, and any fiscal impacts to State Group Insurance would be the result of an increase in approvals of claims. The bill would not impact the self-insured plans.

There is no fiscal impact on the Office of Insurance Regulation.

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, health maintenance organizations (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

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

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.
- 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 contain 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, on behalf of the health insurer, that does not use an online prior authorization form must use a standardized form adopted by the Financial Services Commission 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[6]

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.[7] 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 enrollees.[8]

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 enrollees 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

[4] Section 627.642, F.S.
[5] Section 641.31(4), F.S.
[6] Agency for Health Care Administration, *2018 Legislative Bill Analysis of SB 98* (Oct. 31, 2017) (on file with the Senate Committee on Banking and Insurance).
[7] Part III of ch. 409, F.S., governs the Medicaid program.
[8] 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.)

Medicaid services, which are incorporated by reference into Rule 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, and develops and reviews clinical prior authorization criteria, including step-therapy protocols for drugs that are not on the Medicaid PDL.

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.[9] 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 and protocols related to prescription 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.[10]

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., requires the use of a standard prior authorization form by health insurers. 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 adopted by the Financial Services Commission for authorization of procedures, treatments, or prescription drugs. Currently, Medicaid managed care plans are

[9] See Agency for Health Care Administration Pharmacy Policy available at: http://ahca.myflorida.com/Medicaid/Policy_and_Quality/Policy/pharmacy_policy/index.shtml (last viewed Nov. 5, 2017).
[10] 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 (Rule 59G-1.010, F.A.C.).

required by contract to have electronic authorization processes and are therefore 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 after receiving the request. Within 24 hours after receipt of a request, a managed care plan must respond (deny, approve, or request additional information) to a request for prior authorization for prescription drugs. 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 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 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 prior authorization requests within 24 hours after receipt and within

14 calendar days after initial receipt for routine requests. Current industry standards for utilization review change notices to plan participants or enrollees is 30 days.[11]

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.[12] 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 benefits[13] and other provisions.

The PPACA requires insurers and HMOs that offer qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.[14] In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and other requirements.[15] The federal deadline for insurers and HMOs to submit 2018 annual rates and forms to the Florida Office of Insurance Regulation was May 3, 2017.[16,17] Recently, the U.S. Department of Health and Human Services (HHS) proposed federal regulations that included provisions to provide states with additional flexibility in the definition of EHBs for 2019 and 2020 and increase affordability of health insurance in the individual and small group markets.[18]

Prescription Drug Coverage

For purposes of complying with the federal EHB for prescription drugs, plans must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and

---

[11] Department of Management Services, *2018 Legislative Bill Analysis SB 98* (Oct. 31, 2017) (on file with the Senate Banking and Insurance Committee).
[12] The Patient Protection and Affordable Care Act (Pub. L. No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.
[13] 42 U.S.C. s.18022.
[14] 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 viewed Nov. 5, 2017) for Florida's benchmark plan.
[15] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans,* https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last viewed Nov. 5, 2017).
[16] Office of Insurance Regulation, *Guidance to Insurers*, available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last viewed Nov. 5, 2017).
[17] 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: Nov. 5, 2017).
[18] *See* Proposed Rule, 82 FR 51052 (Nov. 2, 2017). The U.S. Department of Health and Human Services is soliciting comments on different applications of the state mandate policy to the proposed policy for EHB benchmark plan selections that would increase state flexibility, while also being cost effective for states, consumers, and the federal government. For plan years further in the future, the HHS is considering establishing a Federal default definition of EHBs that would better align medical risk in insurance products by balancing costs to the scope of benefits. Available at https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019 (last viewed Nov. 5, 2017).

class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Plans 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. The PPACA also requires plans to implement an internal appeals and independent external review process if an insured is denied coverage of a drug on the formulary.[19]

Plans are required to publish a current 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 insureds, prospective insureds, the state, and the public.[20] Restrictions include prior authorization, step therapy, quantity limits and access restrictions.[21]

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. 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 a plan. In some cases, plans require an insured to use a step therapy protocol for drugs or a medical treatment, which requires the insured to try one drug or medical procedure first to treat the medical condition before the insurer or HMO will cover another drug or procedure for that condition.

III. Effect of Proposed Changes:

Section 1 revises s. 627.42392, F.S., relating to prior authorization by a health insurer. A health insurer is defined as an authorized insurer offering major medical or similar comprehensive coverage, a Medicaid managed care plan, or an HMO. The section defines the term, "urgent care situation," which has the same meaning as in s. 627.42393, F.S. (see section 2, below).

A health insurer or a PBM on behalf of a health insurer is required to provide current prior authorization requirements, restrictions, and forms on a publicly accessible website and in written or electronic format upon request. 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 health insurer or a PBM on behalf of a health insurer intends to amend or implement new prior authorization requirements or restrictions, the health insurer or PBM must:

- Ensure that the new or amended requirements or restrictions are available on their website at least 60 days before the effective date of the changes.

[19] 45 C.F.R. s. 147.136.
[20] 45 C.F.R. s. 156.122(d).
[21] According to Centers for MS, 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).

- Provide notice to policyholders and providers who are affected by the changes at least 60 days before the effective date. Notice may be delivered electronically or by other methods mutually agreed upon by the insured or provider.

These notice requirements do not apply to expansion of coverage.

Health insurers or PBMs on behalf of health insurers must approve or deny prior authorization requests in urgent and nonurgent care circumstances within 24 hours and 72 hours, respectively, after receipt of the prior authorization form. Notice must be given to the patient and the treating provider of the patient.

Section 2 creates s. 627.42393, F.S., relating to step therapy or fail-first protocols. The bill defines the following terms:

- "Fail-first protocol," is a written protocol that specifies the order in which a certain medical procedure, prescription drugs or course of treatment must be used to treat an insured's condition.
- "Health insurer" has the same meaning as provided in s. 627.42392, F.S. (see section 1, above).
- "Preceding prescription drug or medical treatment," is a medical procedure, course of treatment, or prescription drug that must be used pursuant to a health insurer's fail first protocol as a condition of coverage under a health insurance policy or HMO contract to treat an insured's condition.
- "Protocol exception" is a determination by a health insurer that a fail first protocol is not medically appropriate or indicated for treatment of an insured's condition, and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating provider for the insured's condition.
- "Urgent care situation" is an injury or condition of an insured which, if medical care and treatment is not provided earlier than the time generally considered by the medical profession to be reasonable for a nonurgent situation, in the opinion of the insured's treating physician, would seriously jeopardize the insured's life or health or ability to regain maximum function or subject the patient to severe pain that cannot be managed adequately.

A health insurer is required to publish on its website and provide to an insured in writing the procedure for requesting a protocol exception, including the following:

- A description of the manner in which an insured may request a protocol exception.
- The manner and timeframe in which a health insurer is required to authorize or deny a protocol exception request or respond to an appeal to a health insurer's authorization or denial of a request.
- The conditions in which the protocol exception request must be granted.

As is the case for a response to a request for a prior authorization, the health insurer must authorize or deny a protocol exception request or respond to an appeal of a health insurer's authorization or denial of a request within 24 hours after receipt in an urgent care situation; or within 72 hours after receipt in a nonurgent care situation. The health insurer must include a detailed written explanation of the reason for the denial and the procedure to appeal the denial.

A health insurer must grant a protocol exception request if:

- 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 the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment;
- The insured previously received a preceding prescription drug or another prescription drug or medical treatment that is in the same pharmacologic class or that has the same mechanism of action as a preceding prescription drug, respectively, and the drug or treatment lacked efficacy or effectiveness or adversely affected the insured; or
- A preceding prescription drug or medical treatment is not in the best interest of the insured because the insured's use of the drug or treatment is expected to:
  - Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;
  - Worsen the medical condition of the insured that exists simultaneously but independently with the condition under treatment; or
  - Decrease the ability of the insured to achieve or maintain his or her ability to perform daily activities.

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

Section 3 provides that the bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

The bill does not address whether its provisions apply prospectively to future contracts between a person and an insurer or an HMO or to contracts in existence on the effective date of the bill.

Article I, section 10 of the State Constitution provides:

> **Prohibited laws.—**No bill of attainder, ex post facto law or law impairing the obligation of contracts shall be passed.

This bill may potentially be challenged to the extent that its provisions substantially alter existing contracts, In *Pomponio v. Claridge of Pompano Condominium, Inc*., [22] the Florida Supreme Court reviewed a statute which required the deposit of rent into a court registry during litigation involving obligations under a contract lease. The court invalidated the law as an unconstitutional impairment of contract, after applying a three-prong test."[23] The court noted that the inquiry is not required and the law will stand if the court initially finds that the alteration of contractual obligations is minimal.[24] However, a substantial or severe impairment of an existing contract requires the court to consider 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.[25]

In *United States Fidelity & Guaranty Co. v. Department of Insurance,* the Florida Supreme Court followed *Pomponio*.[26] In so doing, the court stated that the overall query involves a balancing of a person's interest to not have his or her contracts impaired, with the state's interest in exercising legitimate police power.[27] As provided in *Pomponio,* the severity of the impairment increases the level of scrutiny.[28]

Relevant to whether an impairment of contract is constitutional is the degree to which the plaintiff's industry had been regulated in the past. If the industry of the plaintiff was already heavily regulated at the time the plaintiff entered into the contract, further regulation is expected, and therefore considered to be reasonable by the court.[29]

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.

---

[22] *Pomponio v. Claridge of Pompano Condominium, Inc.,* 378 So. 2d 774, 779 (Fla. 1979).
[23] *Id*. at 779, 782.
[24] In so doing, the court concluded, "[t]he severity of the impairment measures the height of the hurdle the state legislation must clear." *Id*.
[25] *Id*.
[26] *United States Fidelity & Guaranty Co. v. Department of Insurance,* 453 So. 2d 1355, 1360 (Fla. 1984).
[27] *Id*. at 1360.
[28] *Id*.
[29] *Id*. at 1361.

Insurers and HMOs may experience an indeterminate increase in costs associated with changes in the step therapy protocols provided in the bill, which could increase premiums for purchasers of health insurance, such as consumers,[30] which may include individuals and employers.

The provisions of the bill would not apply to self-insured health plans because plans are preempted from state regulation under the federal Employee Retirement Income Security Act of 1974.

C. Government Sector Impact:

Office of Insurance Regulation[31]

The bill does not have a fiscal impact on the OIR.

Medicaid[32]

According to the agency, the bill 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 agency will use current agency resources to amend the contract. The bill will significantly affect the business (staffing, systems, etc.) and clinical operations of the Medicaid managed care plans. The bill requires the plans to shorten the time to review authorizations, which will increase the administrative costs.

Chapter 409, F.S., does not define urgent care. The bill defines an "urgent care situation" to have the same meaning as in s. 627.42393, F.S. As the Medicaid plans are required to comply with s. 627.42392, F.S., with regard to prior authorization, these proposed changes would impact the SMMC plans. This will require amendments to the SMMC contracts to revise existing contractual definitions of these terms and to incorporate their meanings within the scope of work under the SMMC program. While the definition for urgent care will have a minor operational impact and will not have a fiscal impact to the Medicaid program, the application of the urgent care definition to the proposed authorization timeframes will have both a fiscal and operational impact.

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 or 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. The timely

[30] Office of Insurance Regulation, *2018 Legislative Bill Analysis of SB 98* (Aug. 30, 2017) (on file with the Senate Committee on Banking and Insurance).
[31] *Id.*
[32] Agency for Health Care Administration, *2018 Legislative Bill Analysis of SB 98* (Oct. 31, 2017) (on file with the Senate Committee on Banking and Insurance).

response standards for protocol exceptions will expedite authorization decisions and require the plans to increase their 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.

Florida State Group Insurance/DMS[33]

The State Group Insurance program indicates that the bill would have a fiscal impact on the program. The program's fully insured health maintenance organization (HMO) vendor, Capital Health Plan (CHP), estimated a fiscal impact of $256,000 annually, based upon the need to employ an additional four medical staff and three support staff employees.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Effective Date

The bill provides an effective date of July 1, 2018. Many commercial plans as well as the Division of State Group Insurance, operate their plans on a calendar year basis. Generally, federal regulations relating to private health insurance require annual rate filings to be submitted prior to July 1. For example, the submission deadline for 2018 ACA-compliant form and rate filings in the individual and small group market was May 3, 2017. This deadline was applicable for products sold on and off the exchange.

The agency notes that at the implementation or effective date of the act, July 1, 2018, the agency and newly contracted managed care plans will be in the process of conducting readiness reviews for implementation of the new contracts. Given the magnitude of the changes proposed in the bill (including system changes, staffing changes, etc.) coinciding with the statutorily required reprocurement of the SMMC program, it would pose operational challenges to Medicaid managed care plans to implement such changes by July 1, 2018. 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 January 1, 2019 would align with the full implementation of the new SMMC contracts and allow the agency and their actuaries sufficient time to develop new capitation rates. This would also provide managed care plans with more time to implement any necessary operational changes concurrent with the new contracts, as well as provide the agency with the time needed to modify and execute revised SMMC contracts to reflect the proposed changes.

[33] Department of Management Services, *2018 Legislative Bill Analysis of SB 98* (Oct. 31, 2017) (on file with the Senate Committee on Banking and Insurance).

Implementation

OIR

The provisions of section 1 of the bill apply to health insurers and pharmacy benefit managers on behalf of health insurers. The OIR licenses and regulates health insurers. Insurers may contract with third parties to provide services or functions. Ultimately, the insurer must comply with the provisions of the Insurance Code. The OIR does not license or regulate PBMs. Currently no agency licenses or regulates PBMs. It is unclear whether the health insurer is responsible for the actions of the PBM.

Section 1 of the bill provides that a prior authorization form may not require information that is not necessary for the determination of medical necessity of, or coverage for, the requested medical procedure, course of treatment, or prescription drug. However, it is unclear what information would be deemed "not necessary." This provision may be difficult to enforce. The bill does not provide rulemaking authority for the OIR.

State Group Insurance/DMS[34]

DMS noted concerns of some of its contracted vendors. Specifically, CVS Caremark, a PBM for the State Group Insurance program had concerns regarding lines 83-88, which require "detailed descriptions of requirements and restrictions to obtain prior authorization." CVS Caremark stated that clinical criteria could be specific to each medication and burdensome to a prescriber or member to identify and understand. CVS Caremark also indicated that this language also suggests that the insurer or PBM's confidential and proprietary clinical criteria must be released to the general public, which could be in conflict with what is required by our manufacturer agreements. CVS Caremark raised similar concerns (lines 157-158) regarding the requirement to post publicly the conditions under which the protocol exception request must be granted. CVS Caremark stated that clinical exceptions criteria could be specific to each medication and burdensome to a prescriber or member to identify and understand. Further, CVS Caremark stated that this language also suggests that the insurer or PBM's confidential and proprietary clinical exceptions criteria must be released to the general public which could be in conflict with what is required by CVS Caremark's manufacturer agreements.

Notice of Prior Authorization Changes

Section 1 of the bill requires health insurers or a PBM to provide at least 60 days' prior notice to insureds and physicians prior to implementing new requirements or restrictions to the prior authorization process. 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.

VIII. Statutes Affected:

This bill substantially amends section 627.42392 of the Florida Statutes.

This bill creates section 627.42393 of the Florida Statutes.

[34] *Id.*

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.