

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 1354

INTRODUCER: Banking and Insurance Committee and Senator Grimsley

SUBJECT: Health Care

DATE: April 10, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	Favorable
2.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1354 revises the managed care accountability contract provisions for the statewide Managed Medical Assistance (MMA) contracts under the Statewide Medicaid Managed Care Program (SMMC). It requires plans that establish prescribed drug formularies to offer a range of therapeutic options with at least two products in each therapeutic class. Managed care plans under MMA must also cover any drugs newly approved by the United States Food and Drug Administration (FDA) until the Medicaid Pharmaceutical and Therapeutics Committee can review the drug for inclusion in the formulary. If a drug on a Medicaid managed care plan's formulary is removed or changed, the plan must allow an enrollee to continue that drug if the provider submits a written request that demonstrates the drug is medically necessary and the enrollee meets clinical criteria to receive the drug.

The bill requires MMA managed care plans, health insurers, managed care organizations, and health maintenance organizations and any pharmacy benefit manager under contract with these insurers, to use a standardized prior authorization form adopted by the Financial Services Commission (commission). The form is to be adopted by January 15, 2015. All prior authorization requests for medical procedures, course of treatment, and prescriptions must be submitted using the same standardized two-page form. A form submitted by a provider is deemed approved unless the issuer responds otherwise within two business days.

Managed care plans, health maintenance organizations and insurers, including Medicaid plans, that restrict medications by a step-therapy or fail-first protocol are required to have a clear and convenient process to request an override of the protocol. An override must be granted within

24 hours for certain situations where the prescribing provider believes the drug under the step-therapy or fail-first protocol has been or likely will be ineffective or will cause or will likely cause an adverse reaction. If the provider allows the patient to enter the step-therapy or fail-first protocol, the duration of the process may not exceed an amount deemed appropriate by the provider and if the provider deems it ineffective, the patient is entitled to receive the recommended course of treatment without override approval.

For insurance contracts for reduced rates of payment under s. 627.6471, F.S., the bill requires insurers to post a link on their website's homepage to a list of preferred providers. Changes to that list must be updated within 24 hours.

The bill would have a negative, significant indeterminate impact on the State Employees' Health Trust Fund. The fiscal impact on Medicaid is indeterminate at this time; it is likely to be significant.

II. Present Situation:

Medicaid

Medicaid is a joint federal and state funded program that provides healthcare for low income Floridians. The program is administered by the Agency for Healthcare Administration (AHCA). Over 3.3 million Floridians are currently enrolled in Medicaid. The program's estimated expenditures for Fiscal Year 2012-2013 were approximately \$21 billion.¹ The statutory authority for the Medicaid program is contained in ch. 409, F.S.

Statewide Medicaid Managed Care

In 2011, the Legislature passed HB 7107² creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The SMMC program requires the AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits for the delivery of primary and acute care under the Managed Medical Assistance component (MMA).³ Final approval by the federal government of the 1915(b) Medicaid waiver for the MMA component of SMMC program was received on June 14, 2013.⁴ The AHCA recently begun the waiver renewal process for the period of July 1, 2014, through June 30, 2017.⁵

The AHCA is in the process of implementing the MMA component of SMMC program through which most Medicaid recipients will receive their health care services. The first regional roll-out begins May 1, 2014, and the last is scheduled for August 1, 2014. During the implementation,

¹ Agency for Health Care Administration, *Florida Medicaid*, <http://ahca.myflorida.com/Medicaid/index.shtml> (last visited Nov. 26, 2013).

² See ch. 2011-134, L.O.F.

³ Health and Human Services Committee, Fla. House of Representatives, *PCS HHSC 11-01 Staff Analysis*, p.25, (Mar. 25, 2011).

⁴ See Correspondence between Agency for Health Care Administration and the Centers for Medicare and Medicaid Services, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/06-14-2013_Approval_Letter.pdf (last visited Nov. 21, 2013).

⁵ Agency for Health Care Administration, *Managed Medical Assistance - Federal Authorities*, http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#FCA (last visited Nov. 21, 2013).

existing Medicaid managed care plans will continue until the region they serve transitions to the MMA program.

The AHCA's contracts with the current Medicaid managed care plans allow the plans to develop their own preferred drug list (PDL) and prior authorization processes, including step-therapy and fail-first criteria, which must be approved by the AHCA.⁶ Current managed care plans also have the ability to deny claims for enrollees who were later determined to be ineligible at the time of service despite having issued a prior authorization.⁷

For the first year of the MMA transition, the AHCA is requiring the MMA plans to use the Medicaid PDL. After the first year, the MMA plans may develop a plan-specific PDL for the Agency's consideration, if requested by the Agency at that time.⁸

Patient Protection and Affordable Care Act

In March 2010, the Congress passed and the President signed the Patient Protection and Affordable Care Act (PPACA).⁹ Among its changes to the United States health care system are requirements for health insurers to make coverage available to all individuals and employers. 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 United States 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.¹⁰

Federal regulations for PPACA also govern an enrollee's coverage bought through the exchanges and for non-grandfathered plans.¹¹ If an enrollee's coverage bought with advance premium tax credit for a qualified health plan (QHP)¹² is terminated for non-payment of premium, for example, the regulations provide the enrollee a 3-month grace period before cancellation of coverage.¹³ During the grace period, the insurer must pay claims for services rendered in the first month but may pend claims for the second and third months.¹⁴ If coverage is ultimately

⁶ Agency for Health Care Administration, *2014 Agency Bill Analysis - SB 1354* (Feb. 21, 2014), p. 2, on file with the Senate Health Policy Committee.

⁷ *Id.*

⁸ *Id.*

⁹ 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.

¹⁰ Centers for Medicare and Medicaid Services, *Health Insurance Marketplace - Will I Qualify for Lower Costs on Monthly Premiums?* <https://www.healthcare.gov/will-i-qualify-to-save-on-monthly-premiums/> (last visited Mar. 22, 2014).

¹¹ Certain plans received "grandfather status" under PPACA. A grandfathered health plan is a plan that existed on March 23, 2010, and had at least one person continuously covered for one year. Some consumer protections elements do not apply to grandfathered plans.

¹² A "qualified health plan" is an insurance plan certified by the applicable Health Insurance Marketplace, provides the essential health benefits, established limits on cost sharing and meets other requirements. *See* <https://www.healthcare.gov/glossary/qualified-health-plan/> for more information on qualified health plans.

¹³ 45 CFR 156.270 and 45 CFR 430.

¹⁴ 45 CFR 156.270.

terminated, the termination date is the last day of the first month of the grace period and the insurer may not recoup any claims paid during the first month of the grace period.

The federal regulations do not affect those enrollees who are not enrolled in an exchange plan or do not receive a subsidy. The grace period for these individuals remains at the length required under s. 627.608, F.S., which varies by the length of the premium payment interval. Cancellation of coverage is effective the first day of the grace period if payment is not received.

Step-Therapy or Fail-First Protocols

Step-therapy or fail-first protocols for prescription medication coverage require a member to try a certain drug, usually a generic alternative, before receiving coverage for another drug, usually a branded, more expensive product. Utilization management pharmacy benefit programs were first introduced in the 1980s and became popular with the implementation of tiered co-payment formularies.¹⁵ Typically, step-therapy is applied to a certain drug class with the goal of encouraging generic drug use and decreasing costs without compromising the quality of care.¹⁶ Many step-therapy programs incorporate edits into the system to recognize members through prior claims who have previously received a first step drug so claims for a second step drug are not rejected, but automatically covered.

One outcome of step-therapy programs, however, has been that enrollees who have had a claim rejected do not have a later claim for a later medication in that same class.¹⁷ The process for notifying the patient and prescriber of a step-therapy claim rejection and the resubmission of an alternate medication varies by insurer.

Prior Authorization for Health Care Services

Insurers may require prior authorization for certain services as a cost control and quality measure. Florida has waived requirements for prior authorization for certain services and requires direct access within specified guidelines for certain services such as dermatology.¹⁸ State law currently does not provide a specific standard form or review timeline for a prior authorization process for health care services covered by an insurer, managed care plan or health maintenance organization. Prior authorization is never required for any emergency procedure. Each insurer has established its own prior authorization process and form based on the situation and the type of authorization, such service, course of treatment, or prescription. The state has mandated a standard health claims processing form be adopted by the commission and used under s. 627.647, F.S., by all hospitals and a separate form by all physicians, dentists and pharmacists.

The National Council for Prescription Drug Programs, a non-profit, stakeholder group, proposed new uniform electronic prior authorization (ePA) standards in July 2013. The new ePA

¹⁵ Patrick P. Gleason, PharmD, FCCP, BCPS, *Assessing Step-Therapy Programs: A Step in the Right Direction*, www.amcp.org, Journal of Managed Care Pharmacy, p. 274, <http://www.amcp.org/data/jmcp/273-75.pdf> (April 2007, Vol. 13, No. 3) (last visited Mar. 23, 2014).

¹⁶ *Id.*

¹⁷ Gleason, *supra*, note 15 at 273-274.

¹⁸ See s. 641.31(33), F.S. Provides direct access to dermatologists for up to 5 visits and testing annually.

electronic prescribing standard provides for a two-way, real-time exchange of information for insurers and prescribers.¹⁹

Federal regulations for the Medicaid and Children's Health Insurance Program both 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.²⁰ Both regulations establish that 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 that the extension is in the enrollee's benefit.²¹ Regulations governing the Children's Health Insurance Program provide a deferral to any existing state law on the authorization of health services, if applicable.²²

Preferred Provider Listings

Individuals enrolled in plans licensed under s. 627.6471, F.S., known as a "Preferred Provider Organization" or PPO plans, incur higher out of pocket costs if the provider is out of network. These out of pocket costs can be significant to the consumer. For example, in the standard PPO Option Group Plan for state employees, the enrollee would pay a small copayment for a physician office visit with an in-network provider after the enrollee had met any calendar year deductible, but would incur 40 percent of the costs with an out of network provider for the same service.²³ The state group PPO provider, Florida Blue, provides a list of providers on its website.

Federal regulations require QHPs on the exchanges to make its provider directory available online and to potential enrollees in hard copy, upon request.²⁴ Further guidance from the federal Centers for Medicare and Medicaid Services (CMS) via a draft guidance letter indicates that QHPs must provide a link from the federal marketplace to their network directly where the consumer can view an up-to-date provider directory. The CMS requires the directory to include the location, contact information, specialty, medical group, any institutional affiliations for each provider and whether the provider is accepting new patients.²⁵

¹⁹ Press Release, National Council for Prescription Drug Programs, *New Uniform Electronic Prior Authorization Standard Supplants the Need for Legislation* (March 6, 2014) on file in the Senate Health Policy Committee.

²⁰ See 42 CFR 438.210 (Medicaid) and 42 CFR 495 (Children's Health Insurance Program).

²¹ 42 CFR 438.210.

²² 42 CFR 457.495(d)(2).

²³ Florida Blue, 2014 Benefits, State Employees' PPO Plan, on file with the Senate Health Policy Committee.

²⁴ 45 CFR 156.235(b).

²⁵ Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, *Draft 2015 Letter to Issuers in the Federally-Facilitated Marketplace* (Feb. 4, 2014), pg. 47,

<http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf> (last visited Mar. 23, 2014).

State Group Health 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 providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with Section 125, Internal Revenue Code.

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 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. The State Employees' Prescription Drug Plan covers all PPO and HMO plan members (excluding Medicare Advantage Plans offered exclusively to eligible retirees).

III. Effect of Proposed Changes:

Medicaid Managed Care Program (Section 1)

Section 1 revises s. 409.967, F.S., and requires a Medicaid managed care plan that establishes a prescribed drug formulary or a PDL must provide a broad range of therapeutic options for the treatment of disease consistent with the outpatient population. At least two products in each therapeutic class must be included, if feasible. The AHCA indicates it will be required to amend its existing Medicaid contracts to ensure compliance.²⁶

The managed care plan must also provide coverage through prior authorization for any new drug approved by the Food and Drug Administration until the Medicaid Pharmaceutical and Therapeutics Committee (committee) can review the drug for inclusion on the formulary. The timing of the committee meeting must comply with s. 409.91195, F.S., which requires at least quarterly meetings.

If a managed care plan removes a drug from a plan's formulary, the bill requires the managed care plan to continue the enrollee's receipt of the drug if the provider submits a written request that the drug is medically necessary and meets clinical criteria.

Prior Authorization Requirements (Sections 1, 3, and 7)

Health plans, health insurers, and health maintenance organizations, including those participating under SMMC, will be required, upon adoption by the commission after January 1, 2015, to use a new, standardized prior authorization form for obtaining approval for a medical procedure, course of treatment, or prescription drug benefit. The commission is required to adopt rules prescribing the form. A pharmacy benefit manager under contract with a managed care plan must also comply with this requirement. The form must be available electronically from the commission and on the Medicaid managed care plan, insurer, or health maintenance organization's website. A prior authorization request completed on the standardized form will be deemed approved upon receipt by the managed care plan unless the managed care plan responds within 2 business days.

²⁶ See *supra*, note 6.

The bill adds the prior authorization provisions to existing s. 409.967, F.S., and creates two new sections, ss. 627.6465 and 641.393, F.S.

Medication Protocol Overrides (Sections 1, 4, and 8)

If medications for the treatment of a medical condition are restricted for use through a step-therapy or fail-first protocol by a SMMC plan, an insurer, or a health maintenance organization, the prescribing provider must have access to a clear and convenient process to request an override. An override must be granted within 24 hours if the prescribing provider believes that:

- Based on sound clinical evidence, the preferred treatment required under step-therapy or fail-first protocol has been ineffective in the patient's disease or medical condition; or
- Based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:
 - Is expected or likely to be ineffective based on known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen; or
 - Will cause or will likely cause an adverse reaction or other physical harm to the patient.

If the patient does enroll in the step-therapy or fail-first protocol, the duration of the process may not exceed a period deemed appropriate by the provider. If the provider finds the treatment ineffective, the bill provides that the patient is entitled to receive the recommended course of treatment without requiring the provider to seek an override of the step-therapy or fail-first protocol.

To add the provisions on step-therapy and fail-first protocol for the SMMC program, s. 409.967, F.S., is amended and two new sections, ss. 627.6466 and 641.394, F.S., are created to apply the provisions to insurers and health maintenance organizations.

Payment of Claims (Sections 2 and 6)

Currently, health insurers under s. 627.6131, F.S., and health maintenance organizations under s. 641.3155, F.S., are prohibited from retroactively denying claims because of insured ineligibility more than 1 year after the date of the payment of the claim. The bill requires a health insurer or HMO to notify a provider that an insured or subscriber of a PPACA compliant policy or contract is delinquent in their premium payments at the time of eligibility verification in order to be able to deny a claim if the insured or subscriber fails to pay their premium for a policy or contract. This provision would not apply to grandfathered plans.

Reduced Rate Insurance Contracts - Provider Listings (Section 5)

For contracts for reduced rates of payment, s. 627.6471, F.S., is revised and insurers must post a link on their website's homepage to a list of preferred providers. Changes to the provider list must be updated within 24 hours.

The bill has an effective date of July 1, 2014.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

Under Article VII, section 18(a), Fla. Const., a mandate includes a general bill requiring counties or municipalities to spend funds. Counties and municipalities are not bound by a general law to spend funds or take an action unless the Legislature has determined that such a law fulfills an important state interest and one of the specific exceptions specified in the state constitution applies. The implementation of this bill may require some counties and municipalities to spend funds or take actions regarding health insurance programs for their employees because of the step-therapy provisions, which may increase utilization of more costly brand medications. One of those mandate exceptions is that the law applies to all persons similarly situated, including the state and local governments. This bill may apply to all similarly situated persons, including the state and local governments. Therefore, a finding by the Legislature that the bill fulfills an important state interest would remove the bill from the purview of the constitutional provision.

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:

Consumers may see more timely authorization for certain services, course of treatment, or prescriptions ordered by their health care providers. Health care providers and their patients may also experience less of a burden receiving a brand drug under the step-therapy or fail-first guidelines because patients are provided a statutory mechanism for bypassing step one, if certain indicators are present.

The provisions of the bill would not apply to self-insured plans, which are preempted from state mandates by the federal Employee Retirement Income Security Act (ERISA). In 2011, 58.5 percent of workers with private health coverage were enrolled in self-insured plans.²⁷

Individuals and employers with private insurance coverage may see an increase in out-of-pocket costs or premiums related to the implementation of step-therapy and the prior

²⁷ <https://www.shrm.org/hrdisciplines/benefits/Articles/Pages/Self-Insured-Health-Plans.aspx> (last visited April 4, 2014).

authorization provisions. Insurers use these measures as utilization management and cost control tools and might affect some current policies and procedures of insurers.

Insurers under s. 627.6471, F.S., have an additional administrative impact complying with posting a list of preferred providers to their website and reflecting changes within 24 hours.

C. **Government Sector Impact:**

Medicaid

The fiscal impact to Medicaid is indeterminate at this time. The bill may increase the cost of providing a prescribed drug to Medicaid enrollees because it makes changes to the step-therapy and fail-first requirements for plan enrollees and requires that any drug prescribed or recommended by a provider be approved and reimbursed. The AHCA would also need to modify existing Medicaid managed care contracts to incorporate the revised step-therapy and formulary requirements.

Division of State Group Insurance

According to the Department of Management Services, the bill would have a negative, significant, indeterminate impact on the State Employees' Health Insurance Trust Fund. Excerpts of the fiscal analysis provided by the Division of State Group Insurance of the Department of Management Services are provided below:²⁸

Prior Authorization Forms: The bill's requirement for health plans and pharmacy benefit plans to use a standardized authorization form when requesting a health plan's prior approval of a service or prescription could impede and decrease efficiency for the prior authorization process for both the doctor and the health plan. For example, the two-page form submitted may be incomplete or not have the necessary information to make an informed decision within 2 business days. It is unclear if there is a mechanism to request additional information to make a decision outside of the 2-day window, nor does there appear to be a process for unfavorable decisions or for cases needing same-day decisions (e.g., emergency situations). The 2-day turnaround is shorter than timelines set by the National Committee on Quality Assurance.

Further, drugs and services subject to prior authorization vary greatly among health plans; it would not be possible to design a single prior authorization form that meets every medical and/or prescription drug need or use. The rules for this form are required to be adopted on or before January 1, 2015; however, this is the same day the insurance companies, health maintenance organizations, and pharmacy benefit managers must start using the form.

Online Provider Directory: Regarding the 24-hour timeframe, the bill does not address situations where the provider may end its network status retroactively.

²⁸ Department of Management Services, SB 1354 Analysis (Mar. 25, 2014) on file with Senate Committee on Banking and Insurance).

VI. Technical Deficiencies:

Section 5 of the bill requires insurers to update changes in the list of preferred providers on their website within 24 hours. It is unclear whether the online list will need to be updated within 24 hours of any change in contracts with preferred providers, or may be updated by the end of the next day.

VII. Related Issues:

The bill provides a deadline of on or before January 1, 2015, for the adoption of rules and the adoption of the prior authorization form. It is unclear whether this deadline would provide adequate time for implementation of such prior authorization forms for plans that are on a calendar year.

The bill provides that the “adoption of the prior authorization form by the Financial Services Commission does not constitute a determination that affects the substantial interests of a party under chapter 120.” It is unclear what recourse would be available for affected parties.

Section 1311(d)(3)(B) of PPACA requires states to defray the costs of state-mandated benefits in excess of essential health benefits for individuals enrolled in any qualified health plan either in the individual market or in the small group market. The bill requires health insurers and HMOs to grant step-therapy overrides within 24 hours to providers who believe that step-therapy protocols could be ineffective or harmful. The bill does not address whether the medication must be a covered benefit under the plan. It is unclear whether a plan would be required to pay for an exclusion, such as an experimental or investigational drug because the provider overrides the step-therapy protocol.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967, 627.6131, 627.6471, and 641.3155.

This bill creates the following sections of the Florida Statutes: 627.6465, 627.6466, 641.393, and 641.394.

IX. Additional Information:

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

CS by Banking and Insurance on April 8, 2014:

The CS provides technical, conforming changes and the following changes:

- Eliminates provision that would have prohibited health insurers and health maintenance organizations from retroactively denying claims because of insured ineligibility if the insurer or health maintenance organization provided the insured/subscriber with an identification card, which at the time of service identifies the insured/subscriber as eligible to receive services.

- Requires health insurers and health maintenance organizations to notify a provider that an insured/subscriber is delinquent in their payment of premiums at the time of eligibility verification for services in order to be able to deny a claim if the insured/subscriber does not pay their premium for a PPACA compliant policy or contract.
- Exempts grandfathered plans from the step-therapy and prior authorization provisions.

B. Amendments:

None.