By Senator Gaetz

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A bill to be entitled

An act relating to health care protocols; providing a short title; amending s. 409.967, F.S.; requiring a managed care plan to establish a process by which a prescribing physician may request an override of certain restrictions in certain circumstances; providing the circumstances under which an override must be granted; defining the term "fail-first protocol"; creating s. 627.6466, F.S.; requiring an insurer to establish a process by which a prescribing physician may request an override of certain restrictions in certain circumstances; providing the circumstances under which an override must be granted; defining the term "fail-first protocol"; amending s. 641.31, F.S.; prohibiting a health maintenance organization from requiring that a health care provider use a clinical decision support system or a laboratory benefits management program in certain circumstances; defining terms; providing for construction; creating s. 641.394, F.S.; requiring a health maintenance organization to establish a process by which a prescribing physician may request an override of certain restrictions in certain circumstances; providing the circumstances under which an override must be granted; defining the term "fail-first protocol"; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. <u>This act may be known as the "Right Medicine Right Time Act."</u>

Section 2. Paragraph (c) of subsection (2) of section

409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) *Access.*—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the

availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2.a. Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

b. If a managed care plan restricts the use of prescribed drugs through a fail-first protocol, it must establish a clear and convenient process that a prescribing physician may use to request an override of the restriction from the managed care plan. The managed care plan shall grant an override of the protocol within 24 hours if:

(I) Based on sound clinical evidence, the prescribing provider concludes that the preferred treatment required under the fail-first protocol has been ineffective in the treatment of the enrollee's disease or medical condition; or

(II) Based on sound clinical evidence or medical and scientific evidence, the prescribing provider believes that the

preferred treatment required under the fail-first protocol:

(A) Is likely to be ineffective given the known relevant physical or mental characteristics and medical history of the enrollee and the known characteristics of the drug regimen; or

(B) Will cause or is likely to cause an adverse reaction or other physical harm to the enrollee.

If the prescribing provider follows the fail-first protocol recommended by the managed care plan for an enrollee, the duration of treatment under the fail-first protocol may not exceed a period deemed appropriate by the prescribing provider. Following such period, if the prescribing provider deems the treatment provided under the protocol clinically ineffective, the enrollee is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol. As used in this subparagraph, the term "fail-first protocol" means a prescription practice that begins medication for a medical condition with the most cost-effective drug therapy and progresses to other more costly or risky therapies only if necessary.

3. Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

4. Managed care plans serving children in the care and custody of the Department of Children and Families shall ~~must~~ maintain complete medical, dental, and behavioral health encounter information and participate in making such information available to the department or the applicable contracted

community-based care lead agency for use in providing comprehensive and coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department are ~~shall be~~ the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

Section 3. Section 627.6466, Florida Statutes, is created to read:

627.6466 Fail-first protocols.—If an insurer restricts the use of prescribed drugs through a fail-first protocol, it must establish a clear and convenient process that a prescribing physician may use to request an override of the restriction from the insurer. The insurer shall grant an override of the protocol within 24 hours if:

(1) Based on sound clinical evidence, the prescribing provider concludes that the preferred treatment required under the fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(2) Based on sound clinical evidence or medical and scientific evidence, the prescribing provider believes that the preferred treatment required under the fail-first protocol:

(a) Is likely to be ineffective given the known relevant

physical or mental characteristics and medical history of the insured and the known characteristics of the drug regimen; or

(b) Will cause or is likely to cause an adverse reaction or other physical harm to the insured.

If the prescribing provider follows the fail-first protocol recommended by the insurer for an insured, the duration of treatment under the fail-first protocol may not exceed a period deemed appropriate by the prescribing provider. Following such period, if the prescribing provider deems the treatment provided under the protocol clinically ineffective, the insured is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol. As used in this section, the term "fail-first protocol" means a prescription practice that begins medication for a medical condition with the most cost-effective drug therapy and progresses to other more costly or risky therapies only if necessary.

Section 4. Subsection (44) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(44) A health maintenance organization may not require a health care provider, by contract with another health care provider, a patient, or another individual or entity, to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decisionmaking relating to the use of such

services. This subsection may not be construed to prohibit any prior authorization requirements that the health maintenance organization may have regarding the provision of clinical laboratory services. As used in this subsection, the term:

(a) "Clinical decision support system" means software designed to direct or assist clinical decisionmaking by matching the characteristics of an individual patient to a computerized clinical knowledge base and providing patient-specific assessments or recommendations based on the match.

(b) "Clinical laboratory services" means the examination of fluids or other materials taken from the human body, which examination is ordered by a health care provider for use in the diagnosis, prevention, or treatment of a disease or in the identification or assessment of a medical or physical condition.

(c) "Laboratory benefits management program" means a health maintenance organization protocol that dictates or limits health care provider decisionmaking relating to the use of clinical laboratory services.

Section 5. Section 641.394, Florida Statutes, is created to read:

641.394 Fail-first protocols.—If a health maintenance organization restricts the use of prescribed drugs through a fail-first protocol, it must establish a clear and convenient process that a prescribing physician may use to request an override of the restriction from the health maintenance organization. The health maintenance organization shall grant an override of the protocol within 24 hours if:

(1) Based on sound clinical evidence, the prescribing provider concludes that the preferred treatment required under

the fail-first protocol has been ineffective in the treatment of the subscriber's disease or medical condition; or

(2) Based on sound clinical evidence or medical and scientific evidence, the prescribing provider believes that the preferred treatment required under the fail-first protocol:

(a) Is likely to be ineffective given the known relevant physical or mental characteristics and medical history of the subscriber and the known characteristics of the drug regimen; or

(b) Will cause or is likely to cause an adverse reaction or other physical harm to the subscriber.

If the prescribing provider follows the fail-first protocol recommended by the health maintenance organization for a subscriber, the duration of treatment under the fail-first protocol may not exceed a period deemed appropriate by the prescribing provider. Following such period, if the prescribing provider deems the treatment provided under the protocol clinically ineffective, the subscriber is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol. As used in this section, the term "fail-first protocol" means a prescription practice that begins medication for a medical condition with the most cost-effective drug therapy and progresses to other more costly or risky therapies only if necessary.

Section 6. This act shall take effect July 1, 2016.