By Senator Gaetz

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A bill to be entitled

An act relating to health care; providing that this act shall be known as the "Right Medicine, Right Time Act"; creating s. 402.90, F.S.; creating the Clinical Practices Review Commission; housing the commission, for administrative purposes, within the Division of Medical Quality Assurance of the Department of Health; specifying the composition of, qualifications for appointment to, and standards imposed on commission members; designating the members as public officers; requiring the executive director to submit to the Commission on Ethics a list of certain people subject to public disclosure requirements; providing penalties for failure to comply with such standards; specifying the duties and responsibilities of the commission; amending s. 409.967, F.S.; requiring a managed care plan that establishes a prescribed drug formulary or preferred drug list to provide a broad range of therapeutic options to the patient; requiring a managed care plan to comply with specified procedures; creating s. 627.6051, F.S.; requiring sufficient clinical evidence to support a proposed coverage limitation at the point of service; defining the term "sufficient clinical evidence"; requiring the commission to determine whether sufficient clinical evidence exists and the Office of Insurance Regulation to approve coverage limitations if the commission determines that such evidence exists; providing for the liability of a health insurer and its chief

medical officer for injuries and damages resulting from restricted access to services if the insurer has imposed coverage limitations without the approval of the office; requiring insurers to establish reserves to pay for such damages; amending ss. 627.642 and 627.6699, F.S.; requiring an outline of coverage and certain plans offered by a small employer carrier to include summary statements identifying specific prescription drugs and procedures that are subject to specified restrictions and limitations; requiring insurers and small employer carriers to post the summaries on the Internet; amending s. 627.651, F.S.; conforming a cross-reference; amending s. 627.662, F.S.; specifying that specified provisions relating to coverage limitations on prescription drugs and diagnostic or therapeutic procedures apply to group health insurance, blanket health insurance, and franchise health insurance; amending s. 641.31, F.S.; requiring a health maintenance contract summary statement to include a statement of any limitations on benefits, the identification of specific prescription drugs, and certain procedures that are subject to specified restrictions and limitations; requiring a health maintenance organization to post the summaries on the Internet; prohibiting a health maintenance organization from establishing certain procedures and requirements that restrict access to covered services; exempting limitations that are supported by sufficient clinical evidence; requiring the commission to

evaluate the sufficiency of the evidence and the Office of Insurance Regulation to approve coverage limitations on the basis of the commission's evaluation; providing an effective date.

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

Section 1. This act shall be known as the "Right Medicine, Right Time Act."

Section 2. Section 402.90, Florida Statutes, is created to read:

402.90 Clinical Practices Review Commission.—There is created the Clinical Practices Review Commission, which is a commission as defined in s. 20.03.

(1) The commission shall be housed for administrative purposes in the Division of Medical Quality Assurance of the Department of Health.

(2) The commission shall consist of seven members appointed, subject to confirmation by the Senate, as follows:

(a) Five physicians, one appointed by the Governor, two appointed by the President of the Senate, and two appointed by the Speaker of the House of Representatives, who are currently practicing medicine in this state and have clinical expertise, as evidenced by the following:

1. A doctoral degree in medicine or osteopathic medicine from an accredited school;

2. An active and clear license issued by this state or another state;

3. Board certification in one or more medical specialties;

and

4. At least 15 years of clinical experience.

(b) One individual, appointed by the Governor, with a doctorate in either pharmacology or pharmacy and at least 10 years of experience in research or clinical practice with applicable postlicensure credentials.

(c) One member, appointed by the Governor, with expertise in the analysis of clinical research, evidenced by a doctoral degree in biostatistics or a related field and at least 10 years of experience in clinical research.

(3) A commission member may not currently be an officer, director, owner, operator, employee, or consultant of any entity subject to regulation by the commission. The executive director, senior managers, and members of the commission are subject to part III of chapter 112, including, but not limited to, the Code of Ethics for Public Officers and Employees and the public disclosure and reporting of financial interests pursuant to s. 112.3145. For purposes of applying part III of chapter 112 to the activities of the executive director, senior managers, and members of the commission, such persons shall be considered public officers or employees and the commission shall be considered their agency.

(a) Notwithstanding s. 112.3143(2), a commission member may not vote on any measure that would inure to his or her special private gain or loss; that he or she knows would inure to the special private gain or loss of any principal by whom he or she is retained, or to the parent organization or subsidiary of a corporate principal by which he or she is retained, other than an agency as defined in s. 112.312; or that he or she knows

would inure to the special private gain or loss of a relative or business associate of the public officer. A commission member who is prohibited from voting for such reasons shall publicly state to the assembly, before such a vote is taken, the nature of his or her interest in the matter from which he or she is abstaining from voting and, within 15 days after the vote, disclose the nature of his or her interest as a public record in a memorandum filed with the person responsible for recording the minutes of the meeting, who shall incorporate the memorandum in the minutes.

(b) Senior managers and commission members shall also file the disclosures required under paragraph (a) with the Commission on Ethics. The executive director of the commission or his or her designee shall notify each standing and newly appointed commission member and senior manager of his or her duty to comply with the reporting requirements of part III of chapter 112. At least quarterly, the executive director or his or her designee shall submit to the Commission on Ethics a list of names of the senior managers and members of the commission who are subject to the public disclosure requirements under s. 112.3145.

(c) Notwithstanding s. 112.3148, s. 112.3149, or any other law, an employee or member of the commission may not knowingly accept, directly or indirectly, any gift or expenditure from a person or entity, or an employee or representative of such person or entity, which has a contractual relationship with the commission or which is under consideration for a contract.

(d) An employee or member of the commission who fails to comply with this subsection is subject to the penalties provided

under ss. 112.317 and 112.3173.

(4) The duties and responsibilities of the commission include:

(a) Development and implementation of policies and procedures for the review of prior authorization, step therapy, or other protocols that limit, at the point of service, access to covered services, including diagnostic procedures, pharmaceutical services, and other therapeutic interventions.

(b) Development of any operational policies and procedures that would facilitate the work of the commission, including the establishment of bylaws, the election of a chair, and other administrative procedures.

(c) Determination as to the sufficiency of clinical evidence submitted in support of any proposed coverage limitation.

(d) Preparation of reports and recommendations that document the proceedings of the commission and identify necessary resources or legislative action.

(5) Subject to appropriations, a commission member may receive compensation and per diem and travel expenses as provided in s. 112.061.

Section 3. 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 managed care plan that establishes a prescribed drug formulary or preferred drug list shall:

a. Provide a broad range of therapeutic options for the

treatment of disease states which are consistent with the general needs of an outpatient population. If feasible, the formulary or preferred drug list must include at least two products in each therapeutic class.

b.~~2.~~ ~~Each managed care plan must~~ Publish the ~~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.

3. For enrollees ~~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.

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

5.~~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 is ~~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.

6. Managed care plans shall comply with the procedures for approval of coverage limitations established pursuant to ss. 627.6051 and 641.31(44).

Section 4. Section 627.6051, Florida Statutes, is created to read:

627.6051 Required approval for certain coverage limitations.—

(1) A coverage limitation imposed by the insurer at the point of service must be supported by sufficient clinical evidence proving that the limitation does not inhibit timely diagnosis or effective treatment of the specific illness or condition for the covered patient. The term "sufficient clinical evidence" means:

(a) A body of research consisting of well-controlled studies conducted by independent researchers and published in peer reviewed journals or comparable publications which consistently support the treatment protocol or other coverage limitation as a best practice for the specific diagnosis or combination of presenting complaints.

(b) Results of a multivariate predictive model which indicate that the probability of achieving desired outcomes is not negatively altered or delayed by adherence to the proposed protocol.

(2) The Clinical Practices Review Commission established under s. 402.90 shall determine whether sufficient clinical evidence exists for a proposed coverage limitation imposed by the insurer at the point of service. In each instance in which the commission finds that sufficient clinical evidence exists to support a coverage limitation, the office shall approve the coverage limitation.

(3) If an insurer, without the approval of the office, imposes a coverage limitation at the point of service, including, but not limited to, a prior authorization procedure, step therapy requirement, treatment protocol, or other utilization management procedure that restricts access to covered services, the insurer and its chief medical officer shall be liable for any injuries or damages, as defined in s. 766.202, and economic damages, as defined in s. 768.81(1)(b), that result from the restricted access to services determined medically necessary by the physician treating the patient. An insurer that imposes such a coverage limitation at the point of service shall establish reserves sufficient to pay for such damages.

Section 5. Subsection (2) of section 627.642, Florida Statutes, is amended to read:

627.642 Outline of coverage.—

(2) The outline of coverage must ~~shall~~ contain:

(a) A statement identifying the applicable category of

coverage afforded by the policy, based on the minimum basic standards set forth in the rules issued to effect compliance with s. 627.643.

(b) A brief description of the principal benefits and coverage provided in the policy.

(c) A summary statement of the principal exclusions and limitations or reductions contained in the policy, including, but not limited to, preexisting conditions, probationary periods, elimination periods, deductibles, coinsurance, and any age limitations or reductions.

(d) A summary statement identifying specific prescription drugs that are subject to prior authorization, step therapy, or any other coverage limitation and the applicable coverage limitation policy or protocol. The insurer shall post the summary statement at a prominent and readily accessible location on the Internet.

(e) A summary statement identifying any specific diagnostic or therapeutic procedures that are subject to prior authorization or other coverage limitations and the applicable coverage limitation policy or protocol. The insurer shall post the summary statement at a prominent and readily accessible location on the Internet.

(f) ~~(d)~~ A summary statement of the renewal and cancellation provisions, including any reservation of the insurer of a right to change premiums.

(g) ~~(e)~~ A statement that the outline contains a summary only of the details of the policy as issued or of the policy as applied for and that the issued policy should be referred to for the actual contractual governing provisions.

(h) ~~(f)~~ When home health care coverage is provided, a statement that such benefits are provided in the policy.

Section 6. Subsection (4) of section 627.651, Florida Statutes, is amended to read:

627.651 Group contracts and plans of self-insurance must meet group requirements.—

(4) This section does not apply to any plan that ~~which~~ is established or maintained by an individual employer in accordance with the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, or to a multiple-employer welfare arrangement as defined in s. 624.437(1), except that a multiple-employer welfare arrangement shall comply with ss. 627.419, 627.657, 627.6575, 627.6578, 627.6579, 627.6612, 627.66121, 627.66122, 627.6615, 627.6616, and 627.662(8) ~~627.662(7)~~. This subsection does not allow an authorized insurer to issue a group health insurance policy or certificate which does not comply with this part.

Section 7. Present subsections (7) through (14) of section 627.662, Florida Statutes, are redesignated as subsections (8) through (15), respectively, and a new subsection (7) is added to that section, to read:

627.662 Other provisions applicable.—The following provisions apply to group health insurance, blanket health insurance, and franchise health insurance:

(7) Section 627.642(2)(d) and (e), relating to coverage limitations on prescription drugs and diagnostic or therapeutic procedures.

Section 8. Paragraph (b) of subsection (12) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(12) STANDARD, BASIC, HIGH DEDUCTIBLE, AND LIMITED HEALTH BENEFIT PLANS.—

(b)1. Each small employer carrier issuing new health benefit plans shall offer to any small employer, upon request, a standard health benefit plan, a basic health benefit plan, and a high deductible plan that meets the requirements of a health savings account plan as defined by federal law or a health reimbursement arrangement as authorized by the Internal Revenue Service, which ~~that~~ meet the criteria set forth in this section.

2. For purposes of this subsection, the terms "standard health benefit plan," "basic health benefit plan," and "high deductible plan" mean policies or contracts that a small employer carrier offers to eligible small employers which ~~that~~ contain:

a. An exclusion for services that are not medically necessary or that are not covered preventive health services; ~~and~~

b. A procedure for preauthorization or prior authorization by the small employer carrier, or its designees;

c. A summary statement identifying specific prescription drugs that are subject to prior authorization, step therapy, or any other coverage limitation and the applicable coverage limitation policy or protocol. The carrier shall post the summary statement in a prominent and readily accessible location on the Internet; and

d. A summary statement identifying any specific diagnostic or therapeutic procedures subject to prior authorization or other coverage limitations and the applicable coverage

limitation policy or protocol. The carrier shall post the summary statement in a prominent and readily accessible location on the Internet.

3. A small employer carrier may include the following managed care provisions in the policy or contract to control costs:

a. A preferred provider arrangement or exclusive provider organization or any combination thereof, in which a small employer carrier enters into a written agreement with the provider to provide services at specified levels of reimbursement or to provide reimbursement to specified providers. Any such written agreement between a provider and a small employer carrier must contain a provision under which the parties agree that the insured individual or covered member has no obligation to make payment for any medical service rendered by the provider which is determined not to be medically necessary. A carrier may use preferred provider arrangements or exclusive provider arrangements to the same extent as allowed in group products that are not issued to small employers.

b. A procedure for utilization review by the small employer carrier or its designees.

This subparagraph does not prohibit a small employer carrier from including in its policy or contract additional managed care and cost containment provisions, subject to the approval of the office, which have potential for controlling costs in a manner that does not result in inequitable treatment of insureds or subscribers. The carrier may use such provisions to the same extent as authorized for group products that are not issued to

small employers.

4. The standard health benefit plan shall include:

a. Coverage for inpatient hospitalization;

b. Coverage for outpatient services;

c. Coverage for newborn children pursuant to s. 627.6575;

d. Coverage for child care supervision services pursuant to s. 627.6579;

e. Coverage for adopted children upon placement in the residence pursuant to s. 627.6578;

f. Coverage for mammograms pursuant to s. 627.6613;

g. Coverage for children with disabilities ~~handicapped children~~ pursuant to s. 627.6615;

h. Emergency or urgent care out of the geographic service area; and

i. Coverage for services provided by a hospice licensed under s. 400.602 in cases where such coverage would be the most appropriate and the most cost-effective method for treating a covered illness.

5. The standard health benefit plan and the basic health benefit plan may include a schedule of benefit limitations for specified services and procedures. If the committee develops such a schedule of benefits limitation for the standard health benefit plan or the basic health benefit plan, a small employer carrier offering the plan must offer the employer an option for increasing the benefit schedule amounts by 4 percent annually.

6. The basic health benefit plan must ~~shall~~ include all of the benefits specified in subparagraph 4.; however, the basic health benefit plan must ~~shall~~ place additional restrictions on the benefits and utilization and may also impose additional cost

containment measures.

7. Sections 627.419(2), (3), and (4), 627.6574, 627.6612, 627.66121, 627.66122, 627.6616, 627.6618, 627.668, and 627.66911 apply to the standard health benefit plan and to the basic health benefit plan. However, notwithstanding such ~~said~~ provisions, the plans may specify limits on the number of authorized treatments, if such limits are reasonable and do not discriminate against any type of provider.

8. The high-deductible ~~high deductible~~ plan associated with a health savings account or a health reimbursement arrangement must ~~shall~~ include all the benefits specified in subparagraph 4.

9. Each small employer carrier that provides for inpatient and outpatient services by allopathic hospitals may provide as an option of the insured similar inpatient and outpatient services by hospitals accredited by the American Osteopathic Association if ~~when~~ such services are available and the osteopathic hospital agrees to provide the service.

Section 9. Subsection (4) of section 641.31, Florida Statutes, is amended and subsection (44) is added to that section, to read:

641.31 Health maintenance contracts.—

(4) Each ~~Every~~ health maintenance contract, certificate, or member handbook must ~~shall~~ clearly state all of the services to which a subscriber is entitled under the contract and must include a clear and understandable statement of any limitations on the benefits, services, or kinds of services to be provided, including any copayment feature or schedule of benefits required by the contract or by any insurer or entity that ~~which~~ is underwriting any of the services offered by the health

maintenance organization. The contract, certificate, or member handbook must ~~shall~~ also state where and in what manner the comprehensive health care services may be obtained. The health maintenance organization shall prominently post the statement regarding limitations on benefits, services, or kinds of services provided on its website in a readily accessible location on the Internet. The statement must include, but need not be limited to:

(a) The identification of specific prescription drugs that are subject to prior authorization, step therapy, or any other coverage limitation and the applicable coverage limitation policy or protocol.

(b) The identification of any specific diagnostic or therapeutic procedures that are subject to prior authorization or other coverage limitations and the applicable coverage limitation policy or protocol.

(44) Health maintenance organizations and prepaid health plans are prohibited from establishing prior authorization procedures, step therapy requirements, treatment protocols, or other utilization management procedures that restrict access to covered services unless expressly authorized to do so under this subsection. A coverage limitation imposed by a health maintenance organization or prepaid health plan at the point of service must be supported by sufficient clinical evidence, as defined in s. 627.6051, which demonstrates that the limitation does not inhibit timely diagnosis or optimal treatment of the specific illness or condition for the covered patient.

Section 10. This act shall take effect October 1, 2015.