A bill to be entitled

An act relating to health insurance; providing a short title; amending s. 409.967, F.S.; revising provisions relating to a managed care plan's prescription drug formulary; providing coverage requirements for such formulary; providing for appeal of certain coverage decisions made by managed care plan; restricting certain managed care plans from implementing discriminatory benefit plans; requiring Office of Insurance Regulation to issue annual report; providing requirements for such report; creating ss. 627.6466 and 641.394, F.S., relating to fail-first protocols; providing for appeal of treatment decisions made by health insurers and health maintenance organizations, respectively; creating ss. 627.64996 and 641.229, F.S.; authorizing Office of Insurance Regulation to hold certain public hearings regarding health insurers and health maintenance organizations, respectively; providing nondiscrimination and reporting requirements for health insurers and health maintenance organizations; providing for appeal of certain coverage decisions made by health insurers and health maintenance organizations; providing that certain treatment criteria used by health insurers and health maintenance organizations constitute a violation; providing penalties; creating s. 627.6165, F.S.;

providing that certain health care insurance provisions do not abrogate an insured's general civil and common law rights; providing requirements for certain civil actions brought against an insurer; providing for application of damages and attorney fees in such actions; amending s. 641.3917, F.S.; providing requirements for certain civil actions brought against a health maintenance organization; providing for application of damages and attorney fees in such actions; providing an effective date.

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

Section 1. This act may be cited as the "Florida Patient Protection Act."

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. If a managed care plan establishes a prescription drug formulary or preferred drug list, the managed care plan shall:

(I) Provide a broad range of therapeutic options for the treatment of disease states consistent with the general needs of an outpatient population. When feasible, the formulary or preferred drug list shall include at least two products in a therapeutic class.

(II) Include coverage through prior authorization for each drug newly approved by the United States Food and Drug Administration until the Medicaid Pharmaceutical and Therapeutics Committee reviews such drug for inclusion on the formulary or preferred drug list. The timing of the review must comply with s. 409.91195.

b. Each managed care plan shall ~~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 shall ~~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.~~

c. If a prescription drug on a formulary or preferred drug list is removed or changed, the managed care plan shall permit an enrollee who was receiving the drug to continue to receive the drug if the provider submits a written request that demonstrates that the drug is medically necessary and the enrollee meets clinical criteria to receive the drug.

d. Each managed care plan shall have in place a medical exceptions process that allows enrollees or their authorized representative, which may include the prescribing health care provider, to request and obtain approval of coverage for a clinically appropriate prescription drug when such drug would otherwise not be covered until the enrollee has satisfied a prior authorization restriction, including a step therapy requirement or fail-first protocol, or such drug would not be covered at the prescribed number of doses.

e. For purposes of this paragraph, a prescription drug is "clinically appropriate" to treat the enrollee's disease or medical condition when the health care provider prescribing the drug submits an oral or written statement stating that he or she has determined that the drug is clinically appropriate based on one of the following criteria:

(I) The number of doses available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition, or, based on sound clinical evidence, medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(II) A prescription drug alternative listed as a preferred drug on the formulary or preferred drug list or required to be used in accordance with step therapy requirements:

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on sound clinical evidence, medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.

f. Notwithstanding any other provision of this section, the managed care plan must provide coverage for at least a one month supply of the prescription drug that is the subject of any request under this subparagraph for any new enrollee to ensure continuity of coverage.

g. For purposes of this subparagraph, each managed care plan's medical exceptions process must conform to the following requirements:

(I) Any request for approval of coverage made verbally or in writing shall be reviewed by appropriate health care professionals who shall take into account the specific facts and circumstances of the enrollee's disease or medical condition and whose decisions shall be made using documented review criteria based on sound clinical and medical and scientific evidence.

(II) The managed care plan shall make a decision on a request and notify the enrollee or the enrollee's authorized

representative of the decision as quickly as the enrollee's medical condition requires, but in no event later than 72 hours after receipt of the request, or for circumstances in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability regain maximum function, no later than 24 hours after receipt of the request.

(III) Any denial of a request shall be provided in writing to the insured or the insured's authorized representative and to the insured's prescribing health care provider and shall contain:

(A) The specific reason or reasons for the denial.

(B) A reference to the evidence or documentation, including the clinical review criteria, clinical evidence, and medical and scientific evidence considered in reaching the decision.

(C) A description of the process and procedures for requesting an appeal of the denial.

(IV) Any denial shall be subject to procedures established by the managed care plan pursuant 42 C.F.R. Part 438, Subpart F.

(V) The managed care plan shall provide coverage of a prescription drug that is subject of a request made pursuant to sub-sub-subparagraph (I) during the entire review process as long as the prescription drug continues to be prescribed for the insured and is considered safe for the treatment of the insured's medical condition, until a final decision is made on the appeal.

h. In the case of an exception granted under this paragraph, a managed care plan shall not establish a copayment, coinsurance, or other cost-sharing requirement that exceeds the amount or percentage applicable to preferred brand name drugs.

i. A managed care plan shall provide coverage of a drug approved pursuant to the process established under this paragraph to the enrollee for as long as the prescription drug continues to be prescribed for that enrollee and is considered safe for the treatment of the enrollee's medical condition and the enrollee remains continuously enrolled in the plan.

j. Each managed care plan shall maintain data and upon request, make available to the agency, the following information with respect to medical exceptions requests made under this paragraph:

(I) The total number of medical exceptions requests.

(II) The number of medical exceptions requests approved and denied.

(III) Any other information the agency may request.

k. When medications for the treatment of a medical condition are restricted for use by a managed care plan through a step-therapy or fail-first protocol, the prescribing physician shall have access to a clear and convenient process to request an override of such restriction from the managed care plan. The managed care plan shall grant an override of the protocol within 24 hours under the following circumstances:

(I) The prescribing provider recommends, based on sound

clinical evidence, that the preferred treatment required under step-therapy or 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 step-therapy or fail-first protocol:

(A) Is expected or 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 will likely cause an adverse reaction or other physical harm to the enrollee.

If the prescribing provider allows the enrollee to enter the step-therapy or fail-first protocol recommended by the managed care plan, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If prescribing provider deems the treatment clinically ineffective, the enrollee is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

1. 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.

3. Notwithstanding any provision of state or federal law, no managed care plan shall use treatment guidelines, coverage rules, or criteria for treatment authorization that restrict payment for medically appropriate treatment prescribed by a licensed physician and agreed to by a fully informed individual or his or her advance medical directive or medical power of attorney. Refusing coverage for medically necessary treatment to be rendered to an insured based solely on the insured's life expectancy or the fact that the insured is diagnosed with a terminal condition is a violation of this paragraph.

4. Forms to request a prior authorization shall be made available electronically by the agency and on the website of the managed care plan, and 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 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 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. If a managed care plan contracts with the state to provide an alternative benefit plan that covers essential health benefits required under federal law, the managed care plan shall not use a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates based on an individual's age, expected length of life, race, color, national origin, sex, sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition.

a. For purposes of this subparagraph, elements of a benefit design and the implementation of a benefit design shall include, but not be limited to, consideration of the categories of benefits included, the specific exclusion of named therapies or conditions, the manner in which coverage decisions are made, differential reimbursement rates or cost sharing for covered benefits, clinical prerequisites or heightened administrative requirements based on the patient's disease, disability, quality

or expected length of life, incentive programs, and the burdensomeness or delay of an applicable exceptions process.

b. A managed care plan's use of medical management techniques whose effect is a coverage or exception denial for a treatment ordered by a physician, and that apply only to specified diseases or conditions, or to subsets of patients or subscribers, is not considered reasonable and is not consistent with the requirements of this section unless the medical management techniques are:

(I) Based on accepted best medical practices for treating such disease, condition, or category of patients.

(II) Published in peer-reviewed medical journals or standards of care adopted by medical specialty societies.

7.a. The agency shall issue on the agency website an annual report evaluating the process the agency uses to assess the extent to which a managed care plan that covers essential health benefits employs discriminatory practices. Each report shall explain how, if discriminatory practices are identified by the evaluation, such discrimination is addressed by the state and what steps the agency will use to prevent discriminatory practices in the future.

b. The first annual report shall evaluate specific steps the state has taken to identify a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates, based on criteria including an individual's age, expected length of life, race, color, national

origin, gender, sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition. The first annual report shall assess the types of plan benefit designs submitted to the state and additional efforts that may be taken to ensure a managed care plan covering essential health benefits does not impermissibly impose clinical prerequisites by limiting care available to those who are sicker, or who have a shorter life expectancy, including consideration of benefit design features such as the categories of benefits included, specific exclusion of named therapies or conditions, the manner in which coverage decisions are made, differential reimbursement rates or cost sharing for covered benefits, clinical prerequisites or heightened administrative requirements based on the patient's disease, disability, quality or expected length of life, incentive programs, and the burdensomeness or delay of an applicable exceptions process. To the extent that discriminatory practices are identified in existing plans the report shall identify such practices in detail and shall identify the steps the agency will take to prevent such discriminatory practices.

c. Each subsequent annual report shall detail and evaluate the evolution of the state assessment process and the extent to which discriminatory practices have been identified, mitigated and prevented.

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

627.6466 Fail-first protocols.—When medications for the treatment of a medical condition are restricted for use by an insurer through a step-therapy or fail-first protocol, the prescribing physician shall have access to a clear and convenient process to request an override of such restriction from the insurer. The insurer shall grant an override of the protocol within 24 hours under the following circumstances:

(1) The prescribing provider recommends, based on sound clinical evidence, that the preferred treatment required under step-therapy or 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 step-therapy or fail-first protocol:

(a) Is expected or 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 will likely cause an adverse reaction or other physical harm to the insured.

If the prescribing provider allows the insured to enter the step-therapy or fail-first protocol recommended by the health insurer, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If

prescribing provider deems the treatment clinically ineffective, the insured is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

Section 4. Section 627.64996, Florida Statutes, is created to read:

627.64996 Health insurer accountability.—The Office of Insurance Regulation may on its own initiative or on receipt of a request or complaint hold a public hearing to consider in light of the facts, allegations, and defenses whether it is reasonable to conclude that the provisions of this section are met by a health insurer. When issuing, renewing, or revising the scope of any health insurer's certificate of authority, the office may consider the results of such hearings and the insurer's compliance with this section.

(1) NONDISCRIMINATION.—A health insurer that provides a contract or policy that covers the essential health benefits shall not use a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates based on an individual's age, expected length of life, race, color, national origin, sex, sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition.

(a) For purposes of this section, elements of a benefit design and the implementation of the benefit design relevant for

public hearing shall include, but not be limited to, consideration of the categories of benefits included, the specific exclusion of named therapies or conditions, the manner in which coverage decisions are made, differential reimbursement rates or cost sharing for covered benefits, clinical prerequisites or heightened administrative requirements based on the patient's disease, disability, quality or expected length of life, incentive programs, and the burdensomeness or delay of an applicable exceptions process.

(b) A health insurer's use of medical management techniques whose effect is a coverage or exception denial for a treatment ordered by the patient's physician, and that apply only to specified diseases or conditions, or to subsets of patients or subscribers, is not considered reasonable and is not consistent with the requirements of this section unless the medical management techniques are:

1. Based on accepted best medical practices for treating such disease, condition, or category of patients.

2. Published in peer-reviewed medical journals or standards of care adopted by medical specialty societies.

(2) REPORTING REQUIREMENTS.—Consistent with Section 1302 of the Patient Protection and Affordable Care Act, (Pub. L. No. 111-148), the Office of Insurance Regulation shall issue an annual report, to be published on the Office of Insurance Regulation website, evaluating the process the state has in place to assess the extent to which a health insurer that holds

itself out to the residents of the state as offering a contract or policy that covers the essential health benefits employs discriminatory practices.

(a) Each report shall detail how, if discriminatory practices are identified by this state evaluation, such discrimination is addressed by the state and intended steps to prevent discriminatory practices in the future.

(b) The first annual report shall be issued no later than December 31, 2015, and shall evaluate specific steps the state has taken to identify a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates based on criteria including an individual's age, expected length of life, race, color, national origin, sex, sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition.

(c) The first annual report shall assess the types of plan benefit designs submitted to the state and additional efforts that may be taken to ensure a health insurance contract or policy covering essential health benefits does not impermissibly impose clinical prerequisites by limiting care available to those who are sicker, or who have a shorter life expectancy, including consideration of benefit design features such as the categories of benefits included; specific exclusion of named therapies or conditions; the manner in which coverage decisions are made; differential reimbursement rates or cost sharing for

covered benefits; clinical prerequisites or heightened administrative requirements based on the patient's disease, disability, quality, or expected length of life; incentive programs; and the burdensomeness or delay of an applicable exceptions process. To the extent that discriminatory practices are identified in existing policies or contracts during the course of a plan year, the report shall identify such practices in detail and shall identify steps the state is taking to prevent such discriminatory practices from being approved as part of future plan offerings.

(d) Each subsequent annual report shall be issued on a yearly basis thereafter, and shall detail and evaluate the evolution of the state assessment process and the extent to which discriminatory practices have been identified, mitigated and prevented.

(3) EXCEPTIONS PROCESS.—All health insurers must have an exceptions process in place that provides timely access to medically necessary therapies and covers such drugs during transitions, which may be enforced by the Office of Insurance Regulation.

(a) Required coverage of clinically appropriate drugs not on the formulary.

1. All health insurers shall establish and maintain a medical exceptions process that allows insureds or their authorized representatives, including the prescribing health care provider, to request and obtain approval of coverage for

any clinically appropriate prescription drug when such drug is not covered based on the health insurance contract or policy's formulary; the health insurer is discontinuing coverage of the drug on the health insurance contract or policy's formulary for reasons other than safety or because the prescription drug has been withdrawn from the market by the drug's manufacturer; or such drug would otherwise not be covered until the insured has satisfied a step therapy requirement or would not be covered at the prescribed number of doses.

2. For purposes of this subsection, a prescription drug is "clinically appropriate" to treat the insured's disease or medical condition when the health care provider prescribing the drug submits an oral or written statement stating that he or she has determined that the drug is clinically appropriate based on one of the following criteria:

a. All of the prescription drugs on any tier of the health insurance policy's formulary for treatment for the same condition would not be as effective for the insured as the requested drug, or would have adverse effects for the insured;

b. The number of doses available under a dose restriction for the prescription drug:

(I) Has been ineffective in the treatment of the insured's disease or medical condition; or

(II) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the insured, and known characteristics of the

drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

c. The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(I) Has been ineffective in the treatment of the insured's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the insured, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(II) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the insured.

3. Notwithstanding any other provision of this section, the health insurance contract or policy must provide coverage for at least one month's supply of the prescription drug that is the subject of any request under this subsection for any new insured under the contract or policy to ensure continuity of coverage.

(b) A health insurer's established medical exceptions process must require, at a minimum, the following:

1. Any request for approval of coverage made verbally or in writing at any time shall be reviewed by appropriate health care professionals, who shall take into account the specific

facts and circumstances of the insured's disease or medical condition and whose decisions shall be made using documented review criteria that are based on sound clinical and medical and scientific evidence.

2. The health insurer shall make a decision and notify the insured or the insured's authorized representative of the decision as quickly as the insured's medical condition requires, but in no event later than 72 hours after receipt of the request, or for circumstances in which applying the standard procedure may seriously jeopardize the insured's life, health, or ability regain maximum function, no later than 24 hours after receipt of the request.

3. Any denial of a request shall be provided in writing to the insured or the insured's authorized representative and to the insured's prescribing health care provider, and shall contain:

a. The specific reason or reasons for the denial.

b. A reference to the evidence or documentation, including the clinical review criteria, clinical evidence, and medical and scientific evidence considered in reaching the decision.

c. A description of the process and procedures for requesting independent review of the denial.

4. Any denial of a request shall be subject to independent review if the insured or the insured's authorized representative requests such review verbally or in writing at any time within 60 days after receipt of notification of the denial. The

independent review entity shall make a decision and notify the insured or the insured's authorized representative of the decision as quickly as the insured's medical condition requires, but in no event later than 72 hours after the receipt of the request for review, or for circumstances in which applying the standard procedure may seriously jeopardize the insured's life, health, or ability regain maximum function, no later than 24 hours after receipt of the request for review.

5. The health insurer shall provide coverage of the prescription drug during the entire review process, as long as the prescription drug continues to be prescribed for that insured and is considered safe for the treatment of the insured's medical condition, until a final decision is made by the independent review entity.

(c) In the case of an exception granted under this section with respect to an individual insured, a health insurer shall not establish a copayment, coinsurance, or other cost-sharing requirement that exceeds the amount or percentage applicable to the formulary tier for preferred brand name drugs.

(d) A health insurer shall provide coverage of any drug approved pursuant to the process established under this section to the insured for as long as the prescription drug continues to be prescribed for that insured and is considered safe for the treatment of the insured's medical condition and the insured remains continuously enrolled in the health insurance policy or contract.

(e) The Office of Insurance Regulation shall require each health insurer to maintain written or electronic records sufficient to demonstrate compliance with this section as a condition of certification. Each health insurer shall maintain data and upon request, make available to the Office of Insurance Regulation, the following information with respect to medical exceptions requests made under this subsection:

1. The total number of medical exceptions requests.

2. The number of medical exceptions requests approved and denied.

3. Any other information the Commissioner may request.

(f) A violation of this section may be a basis for any disciplinary action authorized under state law for noncompliance with the requirements for certification.

(4) RIGHT TO TREATMENT.—

(a) Notwithstanding any provision of state or federal law, no health insurer shall use treatment guidelines, coverage rules, or criteria for treatment authorization that restrict payment for medically appropriate treatment prescribed by a licensed physician and agreed to by a fully informed individual or his or her advance medical directive or medical power of attorney.

(b) Refusing coverage for medically necessary treatment to be rendered to an insured based solely on the insured's life expectancy or the fact that the insured is diagnosed with a terminal condition is a violation of this section.

(c) Violations of this section by a health insurer, its agents, or its contractors shall be subject to the remedies and penalties available for unfair or deceptive consumer practices. It is an unfair and deceptive practice to sell or provide health insurance where the financial well-being of the insurer is used to establish coverage and payment rules that deprive a dying individual of dignity and respect.

Section 5. Section 641.229, Florida Statutes, is created to read:

641.229 Health maintenance organization accountability.—The Office of Insurance Regulation may on its own initiative or on receipt of a request or complaint hold a public hearing to consider in light of the facts, allegations, and defenses whether it is reasonable to conclude that the provisions of this section are met by a health maintenance organization. When issuing, renewing, or revising the scope of any health maintenance organization's certificate of authority, the office may consider the results of such hearings and the organization's compliance with this section.

(1) NONDISCRIMINATION.—A health maintenance organization that holds itself out to the residents of this state as providing a contract or policy that covers the essential health benefits shall not use a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates based on a subscriber's age, expected length of life, race, color, national origin, sex,

sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition.

(a) For purposes of this section, elements of a benefit design and the implementation of the benefit design relevant for public hearing shall include, but not be limited to, consideration of the categories of benefits included, the specific exclusion of named therapies or conditions, the manner in which coverage decisions are made, differential reimbursement rates or cost sharing for covered benefits, clinical prerequisites or heightened administrative requirements based on the subscriber's disease, disability, quality or expected length of life, incentive programs, and the burdensomeness or delay of an applicable exceptions process.

(b) A health maintenance organization's use of medical management techniques whose effect is a coverage or exception denial for a treatment ordered by a subscriber's physician, and that apply only to specified diseases or conditions, or to subsets of patients or subscribers, is not considered reasonable and is not consistent with the requirements of this section unless the medical management techniques are:

1. Based on accepted best medical practices for treating such disease, condition, or category of patients.

2. Published in peer-reviewed medical journals or standards of care adopted by medical specialty societies.

(2) REPORTING REQUIREMENTS.—Consistent with section 1302

of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, the Office of Insurance Regulation shall issue an annual report, to be published on the Office of Insurance Regulation website, evaluating the process the state uses to assess the extent to which a health maintenance organization that holds itself out to the residents of the state as offering a contract or policy that covers the essential health benefits employs discriminatory practices.

(a) Each report shall detail how, if discriminatory practices are identified by a state evaluation, such discrimination is addressed by the state and intended steps to prevent discriminatory practices in the future.

(b) The first annual report shall be issued no later than December 31, 2015, and shall evaluate specific steps the state has taken to identify a benefit design or a manner of implementing a benefit design for providing essential health benefits that discriminates based on criteria including a subscriber's age, expected length of life, race, color, national origin, sex, sexual orientation, present or predicted disability, degree of medical dependency, present or predicted diagnosis, disease or health condition.

(c) The first annual report shall assess the types of plan benefit designs submitted to the state and additional efforts that may be taken to ensure a health maintenance organization contract or policy covering essential health benefits does not impermissibly impose clinical prerequisites by limiting care

available to those who are sicker, or who have a shorter life expectancy, including consideration of benefit design features such as the categories of benefits included; specific exclusion of named therapies or conditions; the manner in which coverage decisions are made; differential reimbursement rates or cost sharing for covered benefits; clinical prerequisites or heightened administrative requirements based on a subscriber's disease, disability, quality, or expected length of life; incentive programs; and the burdensomeness or delay of an applicable exceptions process. To the extent that discriminatory practices are identified in existing policies or contracts during the course of a plan year, the report shall identify such practices in detail and shall identify steps the state is taking to prevent such discriminatory practices from being approved as part of future plan offerings.

(d) Each subsequent annual report shall be issued on a yearly basis thereafter, and shall detail and evaluate the evolution of the state assessment process and the extent to which discriminatory practices have been identified, mitigated, and prevented.

(3) EXCEPTIONS PROCESS.—All health maintenance organization must have an exceptions process in place that provides timely access to medically necessary therapies and covers such drugs during transitions, which may be enforced by the Office of Insurance Regulation.

(a)1. All health maintenance organizations shall establish

and maintain a medical exceptions process that allows subscribers or their authorized representatives, including the prescribing health care provider, to request and obtain approval of coverage for any clinically appropriate prescription drug when such drug is not covered based on the health maintenance organization's formulary; the health maintenance organization is discontinuing coverage of the drug on the health maintenance organization contract or policy's formulary for reasons other than safety or because the prescription drug has been withdrawn from the market by the drug's manufacturer; or such drug would otherwise not be covered until the subscriber has satisfied a step therapy requirement or would not be covered at the prescribed number of doses.

2. For purposes of this subsection, a prescription drug is "clinically appropriate" to treat the subscriber's disease or medical condition when the health care provider prescribing the drug submits an oral or written statement stating that he or she has determined that the drug is clinically appropriate based on one of the following criteria:

a. All of the prescription drugs on any tier of the health maintenance organization's formulary for treatment for the same condition would not be as effective for the insured as the requested drug, or would have adverse effects for the insured;

b. The number of doses available under a dose restriction for the prescription drug:

(I) Has been ineffective in the treatment of the

subscriber's disease or medical condition; or

(II) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the subscriber, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

c. The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(I) Has been ineffective in the treatment of the subscriber's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the insured, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(II) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the insured.

3. Notwithstanding any other provision of this section, the health maintenance organization contract or policy must provide coverage for at least 1 month's supply of the prescription drug that is the subject of any request under this subsection for a new subscriber under the contract or policy to ensure continuity of coverage.

(b) A health maintenance organization's established

medical exceptions process must require, at a minimum, the following:

1. Any request for approval of coverage made verbally or in writing at any time shall be reviewed by appropriate health care professionals, who shall take into account the specific facts and circumstances of the subscriber's disease or medical condition and whose decisions shall be made using documented review criteria that are based on sound clinical and medical and scientific evidence.

2. The health maintenance organization shall make a decision and notify the subscriber or the subscriber's authorized representative of the decision as quickly as the subscriber's medical condition requires, but in no event later than 72 hours after receipt of the request, or for circumstances in which applying the standard procedure may seriously jeopardize the subscriber's life, health, or ability regain maximum function, no later than 24 hours after receipt of the request.

3. Any denial of a request shall be provided in writing to the subscriber or the subscriber's authorized representative and to the subscriber's prescribing health care provider, and shall contain:

a. The specific reason or reasons for the denial.

b. A reference to the evidence or documentation, including the clinical review criteria, clinical evidence, and medical and scientific evidence considered in reaching the decision.

c. A description of the process and procedures for requesting independent review of the denial.

4. Any denial of a request shall be subject to independent review if the subscriber or the subscriber's authorized representative requests such review verbally or in writing at any time within 60 days after receipt of notification of the denial, the independent review entity shall make a decision and notify the subscriber or the subscriber's authorized representative of the decision as quickly as the subscriber's medical condition requires, but no later than 72 hours after the receipt of the request for review, or for circumstances in which applying the standard procedure may seriously jeopardize the subscriber's life, health, or ability regain maximum function, no later than 24 hours after receipt of the request for review.

5. The health maintenance organization shall provide coverage of the prescription drug during the entire review process, as long as the prescription drug continues to be prescribed for that subscriber and is considered safe for the treatment of the subscriber's medical condition, until a final decision is made by the independent review entity.

(c) In the case of an exception granted under this section with respect to an individual subscriber, a health maintenance organization shall not establish a copayment, coinsurance, or other cost-sharing requirement that exceeds the amount or percentage applicable to the formulary tier for preferred brand name drugs.

(d) A health maintenance organization shall provide coverage of a drug approved pursuant to the process established under this section to the subscriber for as long as the prescription drug continues to be prescribed for that subscriber and is considered safe for the treatment of the subscriber's medical condition and the subscriber remains continuously enrolled in the health insurance policy or contract.

(e) The Office of Insurance Regulation shall require each health maintenance organization to maintain written or electronic records sufficient to demonstrate compliance with this section as a condition of certification. Each health maintenance organization shall maintain data and upon request, make available to the Office of Insurance Regulation, the following information with respect to medical exceptions requests made under this subsection:

1. The total number of medical exceptions requests.

2. The number of medical exceptions requests approved and denied.

3. Any other information the Commissioner may request.

(f) A violation of this section may be a basis for any disciplinary action authorized under state law for non-compliance with the requirements for certification.

(4) RIGHT TO TREATMENT.—

(a) Notwithstanding any provision of state or federal law, no health maintenance organization shall use treatment guidelines, coverage rules, or criteria for treatment

authorization that restrict payment for medically appropriate treatment prescribed by a licensed physician and agreed to by a fully informed individual or his or her advance medical directive or medical power of attorney.

(b) Refusing coverage for medically necessary treatment to be rendered to a subscriber based solely on the subscriber's life expectancy or the fact that the subscriber is diagnosed with a terminal condition is a violation of this section.

(c) Violations of this section by a health maintenance organization, its agents, or its contractors shall be subject to the remedies and penalties available for unfair or deceptive consumer practices. It is an unfair and deceptive practice to sell or provide health care coverage where the financial well-being of the insurer is used to establish coverage and payment rules that deprive a dying individual of dignity and respect.

Section 6. Section 641.394, Florida Statutes, is created to read:

641.394 Fail-first protocols.—When medications for the treatment of a medical condition are restricted for use by a health maintenance organization through a step-therapy or fail-first protocol, the prescribing physician shall have access to a clear and convenient process to request an override of such restriction from the organization. The health maintenance organization shall grant an override of the protocol within 24 hours under the following circumstances:

(1) The prescribing provider recommends, based on sound

clinical evidence, that the preferred treatment required under step-therapy or 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 step-therapy or fail-first protocol:

(a) Is expected or is likely to be ineffective 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 will likely cause an adverse reaction or other physical harm to the subscriber.

If the prescribing provider allows the subscriber to enter the step-therapy or fail-first protocol recommended by the health maintenance organization, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If the prescribing provider deems the treatment clinically ineffective, the subscriber is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

Section 7. Section 627.6165, Florida Statutes, is created to read:

627.6165 Civil liability.—The provisions of this part are

cumulative to rights under the general civil and common law, and no action of the department or office shall abrogate such rights to damages or other relief in any court.

(1) A person to whom a duty is owed may bring a civil action against a health insurer that issues a policy pursuant to this part or part VII of this chapter if the person suffers damage as a result of the health insurer's failure to provide a covered service when:

(a) The health insurer should have provided such service had it acted in good faith toward its insured and with due regard for the interest of the insured.

(b) In the independent medical judgment of a treating physician, the service is medically necessary.

(2) If a claimant's civil action against a health insurer is successful, the insurer is liable for all of the claimant's damages, or $500 per violation of a provision of this part or part VII of this chapter, whichever is larger, and is liable for the claimant's costs and attorney fees.

Section 8. Section 641.3917, Florida Statutes, is amended to read:

641.3917 Civil liability.—The provisions of this part are cumulative to rights under the general civil and common law, and no action of the department or office shall abrogate such rights to damage or other relief in any court.

(1) A person to whom a duty is owed may bring a civil action against a health maintenance organization if the person

suffers damage as a result of the health maintenance organization's failure to provide a covered service when:

(a) The health maintenance organization should have provided such service had it acted in good faith toward its subscriber and with due regard for the interest of the subscriber.

(b) In the independent medical judgment of a contracted treating physician or other physician authorized by the health maintenance organization, the service is medically necessary.

(2) If a subscriber's civil action against a health maintenance organization is successful, the health maintenance organization is liable for all of the subscriber's damages, or $500 per violation of a provision of this part, whichever is larger, and is liable for the subscriber's costs and attorney fees.

Section 9. This act shall take effect July 1, 2015.