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By the Committees on Rules; Health Policy; and Banking and Insurance; and Senators Mayfield and Harrell

595-04820-19 20191180c3 A bill to be entitled

An act relating to prescription drug formulary consumer protection; creating s. 627.42393, F.S.; requiring insurers issuing individual or group health insurance policies to provide certain notices to current and prospective insureds within a certain timeframe before the effective date of any change to a prescription drug formulary during a policy year; specifying requirements for a notice of medical necessity that an insured's treating physician may submit to the insurer within a certain timeframe; specifying means by which the notice is to be submitted; requiring the Financial Services Commission to adopt a certain rule; specifying a requirement and prohibited acts relating to certain coverage changes by an insurer if the treating physician provides certain certification; providing construction and applicability; providing an exception for certain increases in prescription drug prices by the drug manufacturer; specifying notification requirements for insurers under such circumstances; requiring insurers to maintain a record of formulary changes and submit an annual report to the Office of Insurance Regulation delineating such changes within a certain timeframe; requiring the commission to adopt a certain form by rule; amending s. 627.6699, F.S.; requiring small employer carriers to comply with certain requirements for any change to a prescription drug formulary under the health benefit plan; amending s. 641.31, F.S.;

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requiring health maintenance organizations to provide certain notices to current and prospective subscribers within a certain timeframe before the effective date of any change to a prescription drug formulary during a contract year; specifying requirements for a notice of medical necessity that a subscriber's treating physician may submit to the health maintenance organization within a certain timeframe; specifying means by which the notice is to be submitted; requiring the commission to adopt a certain rule; specifying a requirement and prohibited acts relating to certain coverage changes by a health maintenance organization if the treating physician provides certain certification; providing construction and applicability; providing an exception for certain increases in prescription drug prices by the drug manufacturer; specifying notification requirements for health maintenance organizations under such circumstances; requiring health maintenance organizations to maintain a record of formulary changes and submit an annual report to the office delineating such changes within a certain timeframe; requiring the commission to adopt a certain form by rule; providing a declaration of important state interest; providing an effective date.

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

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Section 1. Section 627.42393, Florida Statutes, is created

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to read:

627.42393 Health insurance policies; changes to prescription drug formularies; requirements.—

- (1) At least 60 days before the effective date of any change to a prescription drug formulary during a policy year, an insurer issuing individual or group health insurance policies in this state shall:
- (a) Provide general notification of the change in the formulary to current and prospective insureds in a readily accessible format on the insurer's website; and
- (b) Notify, electronically or by first-class mail, any insured currently receiving coverage for a prescription drug for which the formulary change modifies coverage and the insured's treating physician, including information on the specific drugs involved and a statement that the submission of a notice of medical necessity by the insured's treating physician to the insurer at least 30 days before the effective date of the formulary change will result in continuation of coverage at the existing level.
- (2) The notice provided by the treating physician to the insurer must include a completed one-page form in which the treating physician certifies to the insurer that coverage of the prescription drug for the insured is medically necessary. The treating physician shall submit the notice electronically or by first-class mail. The insurer may provide the treating physician with access to an electronic portal through which the treating physician may electronically file the notice. The commission shall prescribe a form by rule for the notice.
 - (3) If the treating physician certifies to the insurer, in

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accordance with subsection (2), that the prescription drug is medically necessary for the insured, the insurer:

- (a) Must authorize coverage for the prescribed drug based solely on the treating physician's certification that coverage is medically necessary; and
- (b) May not modify the coverage related to the covered drug by:
 - 1. Increasing the out-of-pocket costs for the covered drug;
 - 2. Moving the covered drug to a more restrictive tier; or
- 3. Denying an insured coverage of the drug for which the insured has been previously approved for coverage by the insurer.
 - (4) This section does not:
- (a) Prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.
- (b) Apply to a grandfathered health plan as defined in s. 627.402, to benefits specified in s. 627.6513(1)-(14), or to any policy issued or delivered between March 23, 2010, and December 31, 2013, inclusive.
- (c) Alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.
- (d) Alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.
- (e) Apply to a Medicaid managed care plan under part IV of chapter 409.
- (5) (a) This section does not apply if a drug manufacturer increases the list price of a prescription drug on the health

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insurer's formulary to the health insurer or the pharmacy
benefit manager after November 1 of the year before the health
insurer's earliest required rate submission date to applicable
state and federal rate review authorities for the succeeding
calendar or policy year.

- (b) However, at least 60 days before the effective date of a formulary change as a result of circumstances described in paragraph (a), the health insurer shall provide general notification of the formulary change to current and prospective insureds in a readily accessible format on the insurer's website; and notify, electronically or by first-class mail, any insured currently receiving coverage for a prescription drug for which the formulary change modifies coverage and the insured's treating physician, including information on the specific drugs involved.
- (6) A health insurer shall maintain a record of any change in its formulary during the calendar or plan year and, within 45 days after the end of the plan year, submit an annual report to the office delineating such changes. The commission shall prescribe a form by rule for such reports.

Section 2. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

- 627.6699 Employee Health Care Access Act.-
- (5) AVAILABILITY OF COVERAGE. -
- (e) All health benefit plans issued under this section must comply with the following conditions:
- 1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage

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continually to a date not more than 63 days before the effective date of his or her new coverage.

- 2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.
- 3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.
- 4. A small employer carrier shall not increase any requirement for minimum employee participation or any

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requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.

- 5. If a small employer carrier offers coverage to a small employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.
- 6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.
- 7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.
- 8. A small employer carrier shall comply with s. 627.42393 for any change to a prescription drug formulary.
- Section 3. Subsection (36) of section 641.31, Florida Statutes, is amended to read:
 - 641.31 Health maintenance contracts.-
- (36) Except as provided in paragraphs (a), (b), and (c), a health maintenance organization may increase the copayment for

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any benefit, or delete, amend, or limit any of the benefits to which a subscriber is entitled under the group contract only, upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The health maintenance organization may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must shall specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period which will be included in the group contract upon renewal. This subsection does not apply to any increases in benefits. The 45-day notice requirement does shall not apply if benefits are amended, deleted, or limited at the request of the contract holder.

- (a) At least 60 days before the effective date of any change to a prescription drug formulary during a contract year, the health maintenance organization shall:
- 1. Provide general notification of the change in the formulary to current and prospective subscribers in a readily accessible format on the health maintenance organization's website; and
- 2. Notify, electronically or by first-class mail, any subscriber currently receiving coverage for a prescription drug for which the formulary change modifies coverage and the subscriber's treating physician, including information on the specific drugs involved and a statement that the submission of a notice of medical necessity by the subscriber's treating physician to the health maintenance organization at least 30 days before the effective date of the formulary change will

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result in continuation of coverage at the existing level.

(b) The notice provided by the treating physician to the insurer must include a completed one-page form in which the treating physician certifies to the health maintenance organization that coverage of the prescription drug for the subscriber is medically necessary. The treating physician shall submit the notice electronically or by first-class mail. The health maintenance organization may provide the treating physician with access to an electronic portal through which the treating physician may electronically file the notice. The commission shall prescribe a form by rule for the notice.

- (c) If the treating physician certifies to the health maintenance organization, in accordance with paragraph (b), that the prescription drug is medically necessary for the subscriber, the health maintenance organization:
- 1. Must authorize coverage for the prescribed drug based solely on the treating physician's certification that coverage is medically necessary; and
- 2. May not modify the coverage related to the covered drug by:
 - a. Increasing the out-of-pocket costs for the covered drug;
 - b. Moving the covered drug to a more restrictive tier; or
- c. Denying a subscriber coverage of the drug for which the subscriber has been previously approved for coverage by the health maintenance organization.
 - (d) Paragraphs (a), (b), and (c) do not:
- 1. Prohibit the addition of prescription drugs to the list of drugs covered under the contract during the contract year.
 - 2. Apply to a grandfathered health plan as defined in s.

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627.402 or to benefits specified in s. 627.6513(1)-(14).

- 3. Alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.
- 4. Alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.
- 5. Apply to a Medicaid managed care plan under part IV of chapter 409.
- (e)1. Paragraphs (a), (b), and (c) do not apply if a drug manufacturer increases the list price of a prescription drug on the health maintenance organization's formulary to the health maintenance organization or the pharmacy benefit manager after November 1 of the year before the health maintenance organization's earliest required rate submission date to applicable state and federal rate review authorities for the succeeding calendar or policy year.
- 2. However, at least 60 days before the effective date of a formulary change as a result of circumstances described in subparagraph 1., the health maintenance organization shall provide general notification of the formulary change to current and prospective subscribers in a readily accessible format on the health maintenance organization's website; and notify, electronically or by first-class mail, any subscriber currently receiving coverage for a prescription drug for which the formulary change modifies coverage and the subscriber's treating physician, including information on the specific drugs involved.
- (f) A health maintenance organization shall maintain a record of any change in its formulary during the calendar or

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291	plan year and, within 45 days after the end of the plan year,
292	submit an annual report to the office delineating such changes.
293	The commission shall prescribe a form by rule for such reports.
294	Section 4. The Legislature finds that this act fulfills an
295	important state interest.
296	Section 5. This act shall take effect January 1, 2020.