By Senator Mayfield

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A bill to be entitled

An act relating to prescription drug coverage; creating s. 627.42394, F.S.; requiring individual and group health insurers to provide notice of prescription drug formulary changes to current and prospective insureds and the insureds' treating physicians; specifying the timeframe and manner in which such notice must be provided; specifying requirements for a notice of medical necessity submitted by the treating physician; authorizing insurers to provide certain means for submitting the notice of medical necessity; requiring the Financial Services Commission to adopt a certain form by rule by a specified date; specifying a coverage requirement and restrictions on coverage modification by insurers receiving such notice; providing construction and applicability; requiring insurers to maintain a record of formulary changes; requiring insurers to annually submit a specified report to the Office of Insurance Regulation; requiring the office to annually compile certain data, prepare a report and make the report publicly accessible on its website, and submit the report to the Governor and the Legislature; creating s. 627.6404, F.S.; requiring insurers to apply certain reductions in out-of-pocket expenses for prescription drugs toward an insured's cost-sharing obligation; creating s. 627.64742, F.S.; defining the term "pharmacy benefit manager"; requiring pharmacy benefit managers to annually file with the office a specified

report relating to payments collected from pharmaceutical manufacturers; requiring the office to publish such reports on its website within a certain timeframe; authorizing the commission to adopt rules; amending s. 627.6699, F.S.; requiring small employer carriers to comply with certain requirements for prescription drug formulary changes; amending s. 641.31, F.S.; requiring health maintenance organizations to provide notice of prescription drug formulary changes to current and prospective subscribers and the subscribers' treating physicians; specifying the timeframe and manner in which such notice must be provided; specifying requirements for a notice of medical necessity submitted by the treating physician; authorizing health maintenance organizations to provide certain means for submitting the notice of medical necessity; requiring the commission to adopt a certain form by rule by a specified date; specifying a coverage requirement and restrictions on coverage modification by health maintenance organizations receiving such notice; providing construction and applicability; requiring health maintenance organizations to maintain a record of formulary changes; requiring health maintenance organizations to annually submit a specified report to the office; requiring the office to annually compile certain data, prepare a report and make the report publicly accessible on its website, and submit the report to the Governor and the Legislature; creating

s. 641.3157, F.S.; requiring health maintenance organizations to apply certain reductions in out-of-pocket expenses for prescription drugs toward a subscriber's cost-sharing obligation; providing applicability; providing a declaration of important state interest; providing an effective date.

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

Section 1. Section 627.42394, Florida Statutes, is created to read:

627.42394 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 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 and 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 the prescription drug for the insured is medically necessary as defined under s. 627.732(2). 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 submit the notice. By January 1, 2021, the commission shall adopt by rule a form for the notice.

(3) If the treating physician certifies to the insurer in accordance with subsection (2) that the prescription drug is medically necessary for the insured, the insurer:

(a) Must authorize coverage for the prescribed drug until the end of the policy year, based solely on the treating physician's certification that the drug is medically necessary; and

(b) May not modify the coverage related to the covered drug during the policy year by:

1. Increasing the out-of-pocket costs for the covered drug;

2. Moving the covered drug to a more restrictive tier;

3. Denying an insured coverage of the drug for which the insured has been previously approved for coverage by the insurer; or

4. Limiting or reducing coverage of the drug in any other way, including subjecting it to a new prior authorization or step therapy requirement.

(4) Subsections (1), (2), and (3) do 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 or to benefits specified in s. 627.6513(1)-(14).

(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 health insurer shall maintain a record of any change in its formulary during a calendar year. By March 1 annually, a health insurer shall submit to the office a report delineating such changes made in the previous calendar year. The annual report must include, at a minimum:

(a) A list of all drugs that were removed from the formulary and the reasons for the removal;

(b) A list of all drugs that were moved to a tier resulting in additional out-of-pocket costs to insureds;

(c) The number of insureds notified by the insurer of a change in the formulary; and

(d) The increased cost, by dollar amount, incurred by insureds because of such change in the formulary.

(6) By May 1 annually, the office shall:

(a) Compile the data in such annual reports submitted by health insurers and prepare a report summarizing the data submitted;

(b) Make the report publicly accessible on its website; and

(c) Submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 2. Section 627.6404, Florida Statutes, is created to read:

627.6404 Application of reductions to insured cost-sharing obligations.—An insurer shall apply any third-party payment, financial assistance, discount, patient voucher, or other reduction in out-of-pocket expenses made by or on behalf of an insured for prescription drugs toward the insured's deductible, copay, cost-sharing responsibility, or out-of-pocket maximum associated with the insured's policy.

Section 3. Section 627.64742, Florida Statutes, is created to read:

627.64742 Pharmacy benefit manager annual reporting.—

(1) As used in this section, the term "pharmacy benefit manager" has the same meaning as provided in s. 627.64741(1). By March 1, 2021, and every March 1 thereafter, each pharmacy benefit manager shall file a report with the office. The report must contain the following information for the immediately preceding calendar year:

(a) The aggregated dollar amount of rebates, fees, price protection payments, and other payments collected from pharmaceutical manufacturers;

(b) The aggregated dollar amount of rebates, fees, price protection payments, and other payments collected from pharmaceutical manufacturers which was passed to health insurers or health maintenance organizations authorized under chapter 624; and

(c) The aggregated dollar amount of rebates, fees, price

protection payments, and other payments collected from pharmaceutical manufacturers which was passed to insureds at the point of sale.

(2) The office shall publish on its website the reports received under subsection (1) within 60 days after receipt.

(3) The commission may adopt rules to administer this section.

Section 4. 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 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 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. 627.42394 for any change to a prescription drug formulary.

Section 5. 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 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, a health maintenance organization shall:

1. Provide 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 and 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 result in continuation of coverage at the existing level.

(b) The notice provided by the treating physician to the health maintenance organization must include a completed one-page form in which the treating physician certifies to the health maintenance organization that the prescription drug for the subscriber is medically necessary as defined under s. 627.732(2). 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 submit the notice. By January 1, 2021, the commission shall adopt by rule a form 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 until the end of the contract year, based solely on the treating physician's certification that the drug is medically necessary; and

2. May not modify the coverage related to the covered drug during the contract year by:

a. Increasing the out-of-pocket costs for the covered drug;

b. Moving the covered drug to a more restrictive tier;

c. Denying a subscriber coverage of the drug for which the subscriber has been previously approved for coverage by the health maintenance organization; or

d. Limiting or reducing coverage of the drug in any other way, including subjecting it to a new prior authorization or step therapy requirement.

(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. 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) A health maintenance organization shall maintain a record of any change in its formulary during a calendar year. By March 1 annually, a health maintenance organization shall submit to the office a report delineating such changes made in the previous calendar year. The annual report must include, at a minimum:

1. A list of all drugs that were removed from the formulary and the reasons for the removal;

2. A list of all drugs that were moved to a tier resulting in additional out-of-pocket costs to subscribers;

3. The number of subscribers notified by the health maintenance organization of a change in the formulary; and

4. The increased cost, by dollar amount, incurred by subscribers because of such change in the formulary.

(f) By May 1 annually, the office shall:

1. Compile the data in such annual reports submitted by health maintenance organizations and prepare a report summarizing the data submitted;

2. Make the report publicly accessible on its website; and

3. Submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 6. Section 641.3157, Florida Statutes, is created to read:

641.3157 Application of reductions to subscriber cost-sharing obligations.—A health maintenance organization shall apply any third-party payment, financial assistance, discount, patient voucher, or other reduction in out-of-pocket expenses made by or on behalf of a subscriber for prescription drugs toward a subscriber's deductible, copay, cost-sharing

responsibility, or out-of-pocket maximum associated with the subscriber's health maintenance contract.

Section 7. This act applies to health insurance policies, health benefit plans, and health maintenance contracts entered into or renewed on or after January 1, 2021.

Section 8. The Legislature finds that this act fulfills an important state interest.

Section 9. This act shall take effect July 1, 2020.