By Senator Grall

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A bill to be entitled

An act relating to drug prices and coverage; creating s. 381.02036, F.S.; requiring the Agency for Health Care Administration to contract with an entity to designate reference price source countries and analyze certain data; defining the term "real gross domestic product per capita"; providing duties for the contracted entity; requiring the agency to publish annually prescription drug reference prices; amending s. 465.0244, F.S.; prohibiting pharmacies from charging cash-paying customers more than the reference prices for prescribed drugs and biological products; providing applicability; creating s. 499.044, F.S.; providing legislative intent; defining the terms "prescription drug" and "drug"; requiring prescription drug manufacturer permitholders to annually report to the agency international drug price data beginning on a specified date; specifying reporting requirements and penalties; amending s. 626.8825, F.S.; defining terms; requiring that contracts between pharmacy benefit managers and pharmacy benefits plans and programs prohibit pharmacy benefit managers from offering and implementing certain formularies; requiring that contracts between pharmacy benefit managers and participating pharmacies allow a specified option in the administrative appeal procedure; amending s. 626.8827, F.S.; prohibiting pharmacy benefit managers from engaging in certain practices relating to pharmacies and pharmacists;

creating s. 627.4231, F.S.; defining terms; requiring certain health insurers to limit covered prescription drug reimbursement to reference prices; requiring that savings from such reimbursement limits be used for certain purposes; providing documentation, assessment, and reporting requirements for such health insurers; providing applicability; requiring the Office of Insurance Regulation and the agency to submit an annual report to the Governor and the Legislature; creating s. 627.42398, F.S.; requiring that certain health insurance policies limit changes to prescription drug formularies under certain circumstances; providing applicability; providing construction; amending s. 627.6699, F.S.; requiring small employer carriers to limit changes to prescription drug formularies; amending s. 641.30, F.S.; requiring health maintenance organizations to comply with requirements on limits on prescription drug reimbursement and on the uses of savings from such limits; amending s. 641.31, F.S.; prohibiting the inclusion of specified provisions in certain health maintenance contracts; providing applicability; providing construction; requiring the Financial Services Commission to adopt certain rules by a specified date; 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 381.02036, Florida Statutes, is created to read:

381.02036 International drug reference pricing.—The Agency for Health Care Administration shall contract with an entity to designate reference price source countries and analyze the data submitted under s. 499.044 to establish the reference price for each prescribed drug.

(1)(a) The list of reference price source countries must include only countries with a real gross domestic product per capita of at least 60 percent of the United States gross domestic product per capita, using international sales, volume, and pricing data for each country. For the purposes of this paragraph, the term "real gross domestic product per capita" means a country's most recent estimate based on purchasing power parity for that country available in the most recent edition of the United States Central Intelligence Agency World Factbook. Countries with single-payer health care systems, which include whole-market government price-setting for prescription drugs, must be excluded. The agency contractor shall reevaluate the designated reference price source countries annually and shall revise the list as needed.

(b) The agency contractor shall weight the reference price benchmark value of the selected reference price source countries and sort the countries into two or more tiers, using an established index measuring the level of health care system market orientation in each country.

(2)(a) The agency contractor shall analyze the data submitted under s. 499.044 to compare prices among source countries using a publicly available, reliable, and consistent

exchange rate source. The agency contractor shall establish the reference price for each prescribed drug, which must be the lowest price, after adjusting for volume and difference in national gross domestic product, identified in the source countries. A reference price is not required to be established for a drug that has a domestic price determined by the contractor to be competitive with foreign prices; however, the agency contractor shall identify and report such drugs and their reference prices to the agency.

(b) The agency contractor shall prioritize drugs that have little or no competition in the domestic market or that have the greatest difference between the domestic price and the reference price, including, but not limited to, brand name and single-source drugs.

(3) The agency contractor shall update the reference prices annually and may reevaluate and update a specific reference price at any time based on a significant change documented by supplemental pricing data submitted by a manufacturer under s. 499.044(3).

(4) The agency contractor shall provide to the agency the reference prices no later than January 1 each year, and the agency shall publish the reference prices online within 10 days after receipt.

Section 2. Subsection (3) is added to section 465.0244, Florida Statutes, to read:

465.0244 Information disclosure; reference prices.—

(3) A pharmacy may not charge a cash-paying customer an amount greater than the reference price established under s. 381.02036 for a prescribed drug or biological product. The limit

on a drug or biological product charge applies only to the drug or biological product itself and does not apply to any dispensing fee.

Section 3. Section 499.044, Florida Statutes, is created to read:

499.044 International drug reference pricing.—

(1) It is the intent of the Legislature that patients and third-party payors in this state should not pay more for prescription drugs than those in international markets.

(2) As used in this section, the term "prescription drug" or "drug" has the same meaning as the term "prescription drug" in s. 499.003 and includes biological products. The term is limited to those prescription drugs and biological products intended for human use.

(3) Beginning October 1, 2026, each prescription drug manufacturer permitholder and nonresident prescription drug manufacturer permitholder shall annually report international prescription drug price data to the Agency for Health Care Administration.

(a) Permitholders shall annually report the actual outpatient payment or reimbursement amounts for each prescribed drug in each reference price source country identified pursuant to s. 381.02036, including amounts paid by both third-party payors, such as insurers and public health coverage programs, and by individual consumers not using third-party payors, net of rebates and other forms of discounts. Permitholders may report to the agency the average payment amounts for each drug for a reference price source country, if weighted by utilization volume and fully documented.

(b) Permitholders may provide supplemental price data at any time during the year, based on price changes in a reference price source country.

(c) Permitholders shall report the data in a format established by the agency in consultation with the contractor established under s. 381.02036.

(d) The penalty for failure to timely report required data is a fine of $10,000 a day for the first 30 days, and permit suspension thereafter until compliance is achieved.

Section 4. Present paragraphs (b), (c) through (f), (g) through (j), and (k) through (x) of subsection (1) of section 626.8825, Florida Statutes, are redesignated as paragraphs (c), (f) through (i), (k) through (n), and (p) through (cc), respectively, paragraph (h) of subsection (2) and paragraph (h) of subsection (3) are amended, and new paragraphs (b), (d), (e), (j), and (o) are added to subsection (1) of that section, to read:

626.8825 Pharmacy benefit manager transparency and accountability.—

(1) DEFINITIONS.—As used in this section, the term:

(b) "Affiliated manufacturer" means a drug or biological product manufacturer that, either directly or indirectly through one or more intermediaries:

1. Has an investment or ownership interest in a pharmacy benefit manager holding a certificate of authority issued under this part;

2. Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

3. Has an investor or a holder of an ownership interest

which is a pharmacy benefit manager holding a certificate of authority issued under this part.

(d) "Biological product" has the same meaning as in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(e) "Biosimilar" has the same meaning as in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(j) "Drug" has the same meaning as in s. 499.003.

(o) "Interchangeable" has the same meaning as in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PHARMACY BENEFITS PLAN OR PROGRAM.—In addition to any other requirements in the Florida Insurance Code, all contractual arrangements executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy benefits covered on or after January 1, 2024, between a pharmacy benefit manager and a pharmacy benefits plan or program must include, in substantial form, terms that ensure compliance with all of the following requirements and that, except to the extent not allowed by law, shall supersede any contractual terms to the contrary:

(h)1. At a minimum, require the pharmacy benefit manager or pharmacy benefits plan or program to, upon revising its formulary of covered prescription drugs during a plan year, provide a 60-day continuity-of-care period in which the covered prescription drug that is being revised from the formulary continues to be provided at the same cost for the patient for a period of 60 days. The 60-day continuity-of-care period commences upon notification to the patient. This requirement does not apply if the covered prescription drug:

a. Has been approved and made available over the counter by the United States Food and Drug Administration and has entered the commercial market as such;

b. Has been removed or withdrawn from the commercial market by the manufacturer; or

c. Is subject to an involuntary recall by state or federal authorities and is no longer available on the commercial market.

2. Prohibit the pharmacy benefit manager from offering or implementing a formulary that requires a covered person to receive a drug or biological product manufactured by an affiliated manufacturer when there is an available generically equivalent drug or an available biological product that is biosimilar to and interchangeable for the prescribed biological product.

3.~~2.~~ Beginning January 1, 2024, and annually thereafter, the pharmacy benefits plan or program shall submit to the office, under the penalty of perjury, a statement attesting to its compliance with the requirements of this subsection.

(3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PARTICIPATING PHARMACY.—In addition to other requirements in the Florida Insurance Code, a participation contract executed, amended, adjusted, or renewed on or after July 1, 2023, that applies to pharmacist services on or after January 1, 2024, between a pharmacy benefit manager and one or more pharmacies or pharmacists, must include, in substantial form, terms that ensure compliance with all of the following requirements, and that, except to the extent not allowed by law, shall supersede any contractual terms in the participation contract to the contrary:

(h) The pharmacy benefit manager shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in s. 627.64741 for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist.

1. The administrative appeal procedure must include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to the pharmacy benefit manager or through a pharmacy service administration organization. The administrative appeal procedure must allow a pharmacy or pharmacist the option to submit a consolidated administrative appeal representing multiple substantially similar claims. The pharmacy or pharmacist must be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

2. The pharmacy benefit manager must respond to the administrative appeal within 30 business days after receipt of the appeal.

3. If the appeal is upheld, the pharmacy benefit manager must:

a. Update the maximum allowable cost pricing information to at least the acquisition cost available to the pharmacy;

b. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;

c. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and

d. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.

4. If the appeal is denied, the pharmacy benefit manager must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug currently in stock at a price below the maximum allowable cost pricing information.

5. Every 90 days, a pharmacy benefit manager shall report to the office the total number of appeals received and denied in the preceding 90-day period, with an explanation or reason for each denial, for each specific drug for which an appeal was submitted pursuant to this paragraph.

Section 5. Subsections (8) and (9) are added to section 626.8827, Florida Statutes, to read:

626.8827 Pharmacy benefit manager prohibited practices.—In addition to other prohibitions in this part, a pharmacy benefit manager may not do any of the following:

(8) Prohibit or restrict a pharmacy or pharmacist from declining to dispense a drug if the reimbursement rate is less than the actual acquisition cost incurred or which would be incurred by the pharmacy or pharmacist.

(9) Reimburse a pharmacy or pharmacist less than it reimburses an affiliated pharmacy or pharmacist, as those terms are defined in s. 626.8825.

Section 6. Section 627.4231, Florida Statutes, is created

to read:

627.4231 Insurance reimbursement of prescribed drugs at reference prices.—

(1) As used in this section, the term:

(a) "Biological product" has the same meaning as in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603, a managed care plan as defined in s. 409.962(10), a health maintenance organization as defined in s. 641.19, or the state group insurance program as established in part I of chapter 110.

(c) "Prescription drug" or "drug" has the same meaning as the term "prescription drug" in s. 499.003 and includes biological products. The term is limited to those prescription drugs and biological products intended for human use.

(2) A health insurer that provides coverage for outpatient prescription drugs shall provide reimbursement for a covered prescription drug for which there is a reference price under s. 381.02036 in an amount no greater than the reference price. This subsection applies to drug reimbursement and does not apply to any covered dispensing or administration fee established under the terms of the provider contract.

(3)(a) Savings generated under subsection (2) must be used to reduce policyholder premiums and cost sharing as defined in s. 627.42391(1). Each health insurer shall document anticipated savings and premium reductions in rate filings beginning with the first rate filing following the availability of reference prices under s. 381.02036.

(b) Each health insurer shall assess the actuarial effect

of the reference pricing under s. 381.02036 for each insurer product for each plan year. Beginning April 1 following the first full plan year in which reference prices under s. 381.02036 apply to prescription drug reimbursement, each health insurer shall submit an annual report on the assessed effect to the Office of Insurance Regulation or the Agency for Health Care Administration, as applicable.

(4) The requirements of this section apply to prescription drug coverage in the Medicaid program established in chapter 409 to the extent a reference price established under s. 381.02036 generates greater savings for the program than that provided by the state supplemental rebate program established under s. 409.912.

(5) Beginning January 1, 2027, and annually thereafter, the Office of Insurance Regulation and the Agency for Health Care Administration shall submit a joint report to the Governor, the President of the Senate, and the Speaker of the House of Representatives detailing the impact of subsections (2), (3), and (4) in the preceding year, including savings realized compared to prescription drug pricing in the United States not using this pricing model, any problems encountered, any barriers to accessing prescription drugs, the domestic and foreign prescription drug market response, the monitoring and evaluation of the impact on prescription drug program or plan beneficiary access, the quality of care, and the program costs.

Section 7. Section 627.42398, Florida Statutes, is created to read:

627.42398 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than at the time of coverage renewal, an individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not, while the insured is taking a prescription drug:

(a) Remove the prescription drug from its list of covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug; the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c; or the drug has been approved and made available over the counter by the United States Food and Drug Administration and has entered the commercial market as such.

(b) Reclassify the drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify the drug to a higher cost-sharing tier during the policy year.

This subsection applies to drugs for which an insurer negotiates a single acquisition price that will be in effect for the entire plan year.

(2) 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 or to benefits set forth 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.

Section 8. 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 may ~~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 may ~~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 limit changes to prescription drug formularies as required by s. 627.42398.

Section 9. Subsection (6) is added to section 641.30, Florida Statutes, to read:

641.30 Construction and relationship to other laws.—

(6) Every health maintenance organization must comply with s. 627.4231.

Section 10. Subsection (36) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(36) 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) Other than at the time of coverage renewal, a health maintenance contract that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not, while the subscriber is taking a prescription drug:

1. Remove the prescription drug from its list of covered drugs during the policy year or contract year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug; the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c; or the drug has been approved and made available over the counter by the United States Food and Drug Administration and has entered the commercial market as such.

2. Reclassify the drug to a more restrictive drug tier or increase the amount that a subscriber must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify the drug to a higher cost-sharing tier during the policy year or contract year.

This paragraph applies to drugs for which a health maintenance organization negotiates a single acquisition price that will be in effect for the entire plan year.

(b) This subsection does not:

1. Prohibit the addition of prescription drugs to the list of drugs covered during the policy year or contract year.

2. Apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth 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.

Section 11. The Financial Services Commission shall adopt rules to implement sections 4 and 5 of this act by January 1, 2027.

Section 12. The Legislature finds that this act fulfills an important state interest by:

(1) Increasing medication adherence and reducing the likelihood that Floridians would choose to forego, substitute, or ration prescribed medication and therapies due to high cost, by helping cost-burdened Floridians acquire prescribed medication and therapies at competitive, market-based prices.

(2) Ensuring that residents of this state do not spend more for the same quantity of a prescription drug than residents of

other countries, by regulating even-handedly and prospectively, in a historically regulated industry, both resident and nonresident drug manufacturers with regard to international price transparency and international reference-based upper-payment limits.

(3) Ensuring that residents of this state are not at a competitive disadvantage compared to residents of other countries, by countering monopolistic and anticompetitive market conditions using international reference-based upper-payment limits regardless of the incidental effect experienced if other states adopt similar legislation.

(4) Maximizing the number of residents of this state with commercial health plan coverage who can access competitive, market-based prices without interfering with nationally uniform plan administration.

(5) Regulating state-licensed activity and establishing a competitive market without depriving drug manufacturers of reasonable opportunities to profit from their investments, by normalizing both the drug prices paid by residents of this state with those the manufacturers accept in other countries and the profit they benefit from in those countries.

Section 13. This act shall take effect July 1, 2026.