By Senator Gruters

22-01113B-24 20241750__

A bill to be entitled

An act relating to international drug reference pricing; creating s. 499.044, F.S.; providing legislative policy; requiring prescription drug manufacturer permitholders to annually report certain international price data to the Agency for Health Care Administration; providing for administrative enforcement by a specified fine and permit suspension; requiring the agency to contract with an entity to designate reference price source countries and establish the reference prices for prescription drugs based on certain criteria; requiring the agency contractor to reevaluate the designated reference prices source countries annually and revise, as needed; requiring the agency contractor to weigh the reference price benchmark value of such countries in two or more tiers, using specified criteria; providing applicability; defining the term "real gross domestic product per capita"; requiring the agency contractor to analyze specified data to compare prices among source countries using a specified exchange rate source; requiring the agency contractor to establish the reference price for prescribed drugs or products; requiring that such price be the lowest price after making certain adjustments; requiring the agency contractor to update the reference prices annually and permitting reevaluation and updates at any time in certain circumstances; requiring the agency contractor to provide the reference prices by a specified date

each year; requiring the agency to publish the prices online within a specified time; amending s. 465.0244, F.S.; requiring pharmacies to charge no more than the reference price for cash-paying patients; providing applicability; amending s. 627.6044, F.S.; requiring certain health insurers to provide reimbursement for certain prescription drugs no higher than the reference price; providing applicability; requiring health insurers to use certain savings to offset certain payer costs; requiring each health insurer to document anticipated savings and premium reductions in rate filings following the availability of reference prices; requiring each health insurer to assess the actuarial effect of the reference pricing program for each insurer product for each plan year; requiring each health insurer to submit an annual report on the assessed effect of such program to the Office of Insurance Regulation or the Agency for Health Care Administration; providing applicability; requiring the Office of Insurance Regulation and the Agency for Health Care Administration to annually submit a joint report to the Governor and the Legislature by a specified date; amending s. 641.30, F.S.; requiring every health maintenance organization to comply with the provisions of a specified section; providing an effective date.

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

Section 1. Section 499.044, Florida Statutes, is created to read:

499.044 International Drug Reference Pricing.—

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

(2) Beginning October 1, 2025, 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 report the actual outpatient payment or reimbursement amounts for each prescribed drug in each reference price source country identified under this subsection, including amounts paid by both third- party payers such as insurers and government benefit programs and by individual consumers not using third-party payers, net of rebates and other forms of discounts. Permitholders may report the average payment amounts for each drug for a reference price source country, if weighted by utilization volume and fully documented to the agency.

(b) Permitholders may provide supplemental pricing data at any time during the year, based on a pricing 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 this subsection.

(d) Failure to timely report required data shall result in a fine of $10,000 a day for the first 30 days, and permit

suspension thereafter until compliance is achieved.

(3) The agency shall contract with an entity to designate reference price source countries and analyze the data submitted under subsection (2) to establish the reference price for each prescribed drug or product. The agency contractor shall reevaluate the designated reference price source countries annually and revise, as needed. The agency contractor shall weigh the reference price benchmark value of the selected reference price source countries in two or more tiers, using an established index measuring the level of health care system market orientation in each country.

(a) Reference price source countries shall include only countries with a real gross domestic product per capita of at least 40 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 subsection, "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 systems, which include whole-market government price-setting for prescription drugs, shall be excluded.

(b) The agency contractor shall analyze the data submitted under subsection (2) 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 or product, which shall be the lowest price, after adjusting for volume and difference in

national gross domestic product, identified in the source countries. 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 paragraph (2)(b).

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

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

465.0244 Information disclosure and reference pricing.—

(3) A pharmacy shall charge a cash-paying patient an amount no greater than the reference price for a prescribed drug or product with a reference price established under s. 499.044. This requirement applies to product reimbursement, and does not apply to any dispensing fee.

Section 3. Subsections (3) and (4) are added to section 627.6044, Florida Statutes, to read:

627.6044 Use of a specific methodology for payment of claims.—

(3) A health insurer, as defined by s. 627.4301, which provides coverage for outpatient prescribed drugs and products shall provide reimbursement for a covered prescribed drug for which there is a reference price under s. 499.044 in an amount no greater than the reference price. This subsection applies to product reimbursement, and does not apply to any covered dispensing or administering fee established under the terms of the provider contract.

(a) Savings generated by this subsection must be used to reduce policyholder cost sharing and premiums. 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. 499.044.

(b) Each health insurer shall assess the actuarial effect of the reference pricing program in s. 499.044 for each insurer product for each plan year. Beginning April 1 following the first full plan year in which reference prices under s. 499.044 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.

(c) The requirements of this subsection apply to prescription drug coverage in the Medicaid program established in chapter 409 to the extent a reference price established under s. 499.044 generates greater savings for the program than that provided by the state supplemental rebate program established under s. 409.912.

(d) The requirements of this subsection apply to prescription drug coverage in the state group insurance established by part I of chapter 110.

(4) Beginning January 1, 2026, 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 subsection (3) in the preceding year, including savings realized compared to prescription drug pricing in the United States not using this

pricing model, any problems encountered, barriers to access to prescription drugs, domestic and foreign prescription drug market response, monitoring and evaluating the impact on prescription drug program or plan beneficiary access, quality of care, and program costs.

Section 4. 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. 627.6044(3).

Section 5. This act shall take effect July 1, 2024.